"COMPARATIVE ANALYSIS OF COLPOSCOPIC VIA, VILI, LIQUIPREP TM AND CONVENTIONAL PAP SMEAR WITH HISTOPATHOLOGY AS GOLD STANDARD"

DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT
FOR
M.D DEGREE
BRANCH - II
OBSTETRICS & GYNECOLOGY,
MADRAS MEDICAL COLLEGE,
CHENNAI - 3.

THE TAMILNADU DR.M.G.R. MEDICAL UNIVERSITY

MADRAS MEDICAL COLLEGE & HOSPITAL

CHENNAI - 1.

APRIL 2013

CERTIFICATE

This is to certify that the dissertation entitled "**COMPARATIVE ANALYSIS OF COLPOSCOPIC VIA, VILI, LIQUIPREP TM AND CONVENTIONAL PAP SMEAR WITH HISTOPATHOLOGY AS GOLD STANDARD" AT ISO-KGH** is a bonafide work done by **Dr.K.SABARI.** in the Institute of Social Obstetrics, Govt. Kasturba Gandhi hospital(Madras Medical College) Triplicane , Chennai in partial fulfillment of the university rules and regulations for award of MD degree in Obstetrics and Gynecology under my guidance and supervision during the academic year 2010-2013.

Prof. DR.V.KANAGASABAI M.D.,
DEAN,
Madras Medical College,
Rajiv Gandhi Govt. general hospital
Chennai-3

Prof. DR. S.DILSHATH.. M.D., DGO.
Director and Superintendent
Institute of Social Obstetrics,
Govt Kasturba Gandhi hospital for Women and children,
Madras medical college,
Chennai – 3

Prof. DR.RAMANI RAJENDRAN, M.D., DGO.
Guide
Institute of Social Obstetrics,
Govt Kasturba Gandhi Hospital for Women and Children,
Madras Medical College,
Chennai. 3.

DECLARATION

I solemnly declare that this dissertation entitled **"COMPARATIVE ANALYSIS OF COLPOSCOPIC VIA, VILI, LIQUIPREP TM AND CONVENTIONAL PAP SMEAR WITH HISTOPATHOLOGY AS GOLD STANDARD "** is a bonafide work done by me at The Institute Of Social Obstetrics, Govt Kasturba Gandhi Hospital, Madras MedicalCollege during the year 2010-2013 under the guidance and supervision of, **Prof.Dr.RAMANIRAJENDRAN MD.,DGO.** This dissertation is submitted to the TamilNadu Dr.M.G.R.Medical University towards the partial fulfillment of requirements for the award of M.D.Degree in Obstetrics and Gynaecology(Branch-II).

Place:Chennai-3

Date:

Signatureof Candidate

Dr.K.SABARI M.B.B.S,
PostGraduateStudent
InstituteOf Social Obstetrics,
Govt.Kasturba Gandhi Hospital
Chennai

Prof. DR.RAMANI RAJENDRAN.M.D., DGO.
Guide,
InstituteOf Social Obstetrics,
Govt.Kasturba Gandhi Hospital
Chennai.

.

ACKNOWLEDGEMENT

I extend my gratitude to the **Dean Prof. Dr.V.KANAGASABAI M.D.,** Madras Medical College, for his kind permission to do this dissertation and to use the hospital resources for this study.

I would like to express my sincere gratitude to **DIRECTOR Prof**.**Dr. S.DHILSATH M.D.,D.G.O.,** for her guidance and encouragement.

I am extremely thankful to **Prof**.**Dr**. **RAMANI RAJENDRAN M.D., D.G.O.,** for her guidance and co-operative with extreme gratitude. I express my indebtedness to her for her motivation and advice which enabled me to complete this work.

I am extremely thankful to Professor of Pathology **Dr. K.RAMA**. **M.D.,** for her guidance and co-operation.

I would always remember with extreme sense of thankfulness for the co-operation of **Colposcopy department staffs** and **Pathology department staffs**.

I am immensely grateful to the generosity shown by the **patients** who participated in the study.

I extend my profound gratitude to **all unit Chiefs, Registrar, Assistant Professors** for their boundless affection and support for my study.

I thank **Mr.R.Ravanan**, Statistician, who helped me for statistical analysis.

INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI -3

Telephone No : 044 25305301
Fax : 044 25363970

CERTIFICATE OF APPROVAL

To
Dr. K. Sabari
PG in MDOG
Madras Medical College, Chennai -3

Dear Dr. K. Sabari

The Institutional Ethics committee of Madras Medical College, reviewed and discussed your application for approval of the proposal entitled " Comparative analysis of COLOSCOPIC VIA VILI Liquiprep TM and conventional pap smear with histopathology as gold standard" No. 13012012.

The following members of Ethics Committee were present in the meeting held on 27.01.2012 conducted at Madras Medical College, Chennai -3.

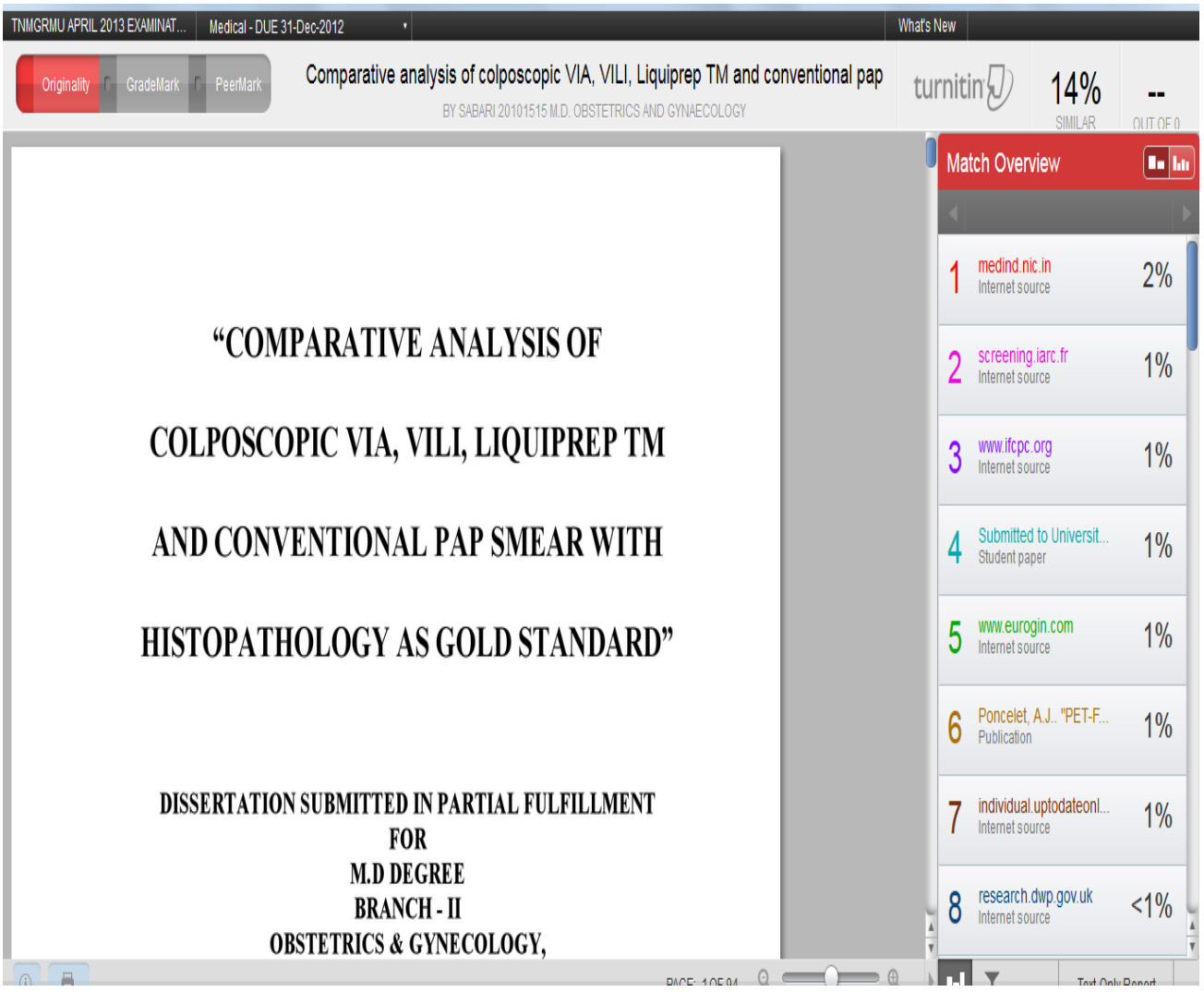
1.	Prof. S.K. Rajan. MD	-- Chairperson
2	Prof. Pregna B. Dolia MD Vice Principal, Madras Medical College, Chennai -3 (Director , Institute of Biochemistry, MMC, Ch-3)	-- Member Secretary
3.	Prof. B. Kalaiselvi. MD Prof of Pharmacology ,MMC, Ch-3	-- Member
4.	Prof. Shruti Kamal MS Prof of Surgery, Madras Medical College , Ch-3	-- Member
5.	Thiru. S. Govindsamy. BA BL	-- Lawyer

We approve the proposal to be conducted in its presented form.

Sd/ Chairman & Other Members

The Institutional Ethics Committee expects to be informed about the progress of the study, and SAE occurring in the course of the study, any changes in the protocol and patients information / informed consent and asks to be provided a copy of the final report.

Member Secretary, Ethics Committee


TNMGRMU APRIL 2013 EXAMINAT...
Medical - DUE 31-Dec-2012
What's New
Originality
GradeMark
PeerMark
Comparative analysis of colposcopic VIA, VILI, Liquiprep TM and conventional pap
BY SABARI 20101515 M.D. OBSTETRICS AND GYNAECOLOGY
turnitin
14%
SIMILAR
--
OUT OF 0
"COMPARATIVE ANALYSIS OF
COLPOSCOPIC VIA, VILI, LIQUIPREP TM
AND CONVENTIONAL PAP SMEAR WITH
HISTOPATHOLOGY AS GOLD STANDARD"
DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT
FOR
M.D DEGREE
BRANCH - II
OBSTETRICS & GYNECOLOGY,
Match Overview
1 medind.nic.in Internet source 2%
2 screening.iarc.fr Internet source 1%
3 www.ifcpc.org Internet source 1%
4 Submitted to Universit... Student paper 1%
5 www.eurogin.com Internet source 1%
6 Poncelet, A.J.. "PET-F... Publication 1%
7 individual.uptodateonl... Internet source 1%
8 research.dwp.gov.uk Internet source <1%

S.No		ABBREVIATIONS
1	CIN	Cervical Intra epithelial Neoplasia
2	HSIL	High grade Squamous Intra epithelial Lesion
3	LSIL	Low grade Squamous Intra epithelial Lesion
4	NIL	Negative for Intra epithelial Lesion
5	US	Unsatisfactory
6	ASCUS	Atypical Squamous Cells of Undetermined Signifcance
7	VIA	Visual Inspection of Acetic acid
8	VILI	Visual Inspection of Lugol's Iodine
9	TZ	Transformation Zone
10	SCJ	Squamo Columnar Junction
11	ECC	Endo Cervical Curettage
12	LBC	Liquid Based Cytology
13	LCB	Last Child Birth
14	PPV	Positive Predictive Value
15	NPV	Negative Predictive Value
16	TP	True Positive
17	TN	True Negative

INTRODUCTION

Female genital tract is one of the most common places for primary malignant disease, among that cervix is the most common site affected by cancer. Worldwide cervical carcinoma continuous to be a significant health care problem. In developing countries ,cancer cervix is the most prevalent cancer .It has long preinvasive course and easily preventable by early detection and treatment.

The gynecologists and primary health care providers to women are familiar with vaccine programmes, screening techniques, diagnostic procedures, risk factors for cervical cancer and management of pre invasive disease. Improved patient education also contributed to improve the screening programmes.

Pre invasive lesions progress slowly over 15-20 years to invasive cancer. Cervix is easily accessible to effective screening tests. It is also preventable malignancy and screening tests identify the pre invasive neoplastic condition in asymptomatic women.

Colposcopy is a study of the subtle changes in the vascular pattern of the cervix, while cytology is a study of morphological changes in the cell. Excellent visualization of the cervix and vaginal portion is essential in colposcopy. The transformation zone should be circumferentially visualized. The use of a green filter helps to enhance the visualization of vascular abnormalities. After application of 5% acetic acid and lugol's iodine over the

cervix and the abnormal areas are identified and treated according to the findings.

The colposcopy, Pap smear, Liquid based cytology, colposcopically directed biopsy are the four methods by which the cervix can be studied for evidence of early malignant change. They are simple OPD procedures requires no anesthesia.

AIM OF THE STUDY

1. To compare the efficiency of COLPOSCOPIC VIA, VILI, LIQUIPREP TM and conventional pap smear; as screening procedure for carcinoma cervix.

2. To study the correlation between cytological and histological findings with cervical biopsy as gold standard.

3. To study the correlation between colposcopy and histological findings with cervical biopsy as gold standard.

4. To compare the efficacy between conventional pap smear with liquid based cytology smear.

5. To compare the cytological and visual inspection findings with colposcopic directed biopsies.

6. To evaluate the sensitivity and specificity of colposcopy versus cytological study in early detection of lesions.

REVIEW OF LITERATURE

The colposcopic procedure was developed in 1925 by German physician Hinselmann associated with Dr. Helmut Wirths.(1)

In 1928, Walter Schillar invented the Schiller's test. He found that weak iodine solution would stain the glycogen in normal cervical squamous epithelium and result in iodine positive area with dark mahogany brown colour, leaving the other areas with lesions unstained.(1)

In 1934, Sacks complained that this cumbersome equipment leads to failure of colposcopy

In 1943,Papanicolaou and Trait , Published their book on cancer diagnosis by vaginal smear. They discovered that precancerous and cancerous cells could be identified in cytologic samples from vaginal samples. This let to the publication of the first book in the papsmear test in 1941.In addition to the collection of the cervical sample improves the sample quality.(27)

American cancer society recognised Pap smear test as an effective cervical cancer screening method in 1945.(28)

In 1947, Ayre introduced the spatula for sampling the cervix.

In 1956, Hinselmann invented the video colposcopy.

Navrratil indicated that by combination of cytologic screening with colposcopy, it was possible to increase the accuracy rate of early cancer detection by 99%.

Richat in 1967, introduced the term cervical Intraepithelial neoplasla. In 1967, Coppleson and Reid decribed the colposcopic features of immature metaplasia.(19)

Stafi developed colposcopic terminologies in 1970.

British colposcopic group was formed in 1971. Coppleson, Pixely and Reid published their first edition of colposcopic text. It established the importance of transformation zone.(19)

IFCPC standardized the colposcopic terminologies in 1975.It introduced the international nomenclature for colposcopic findings and it made rapid adoption of colposcopy world wide.

Evaluation of cervical lesions by the combined use of colposcopy, cytology and cervical biopsy by Usha saraiya and Maya Lulla in their Colposcopy clinic at Mumbai in 1984.It showed pick up rate of cervical cancer in Colposcopy study alone was 13% in non-suspicious group.

The incidence of cancer cervix decreased by almost 70% in the period of 1955 – 1980 by using pap smear as a single screening method in America

In 1988, Duggan *et al* studied the natural history of CIN I lesions.(9)

De Pale (Italy) published a manual on Colposcopy in 1990 for the treatment of lower genital disease.

In 1993, Simmons, evaluated that smoking is one of the causes for cervical cancer and suggesting that smoking modified the DNA in cervical epithelial cells that leads to the development of cervical cancer.

In 1997, Gullota, Margarati and Rabihi studied the correlation among Colposcopy, cytology and biopsy in the diagnosis of precancerous lesions of the cervix. The Sensitivity for the detection of CIN was 70% with cytology sample and 92% with Colposcopy.

In 1998, Mitchel *et al* studied the role of colposcopy for the diagnosis of CR4. He found that the sensitivity of diagnostic colposcopy with all grade cervical dysplasias was 96% and the specificity was 48%.(21)

In 1988, Feinstein *et al* evaluated that the pre and post procedure value of endocervical curettage in the detection of CIN and cancer cervix. He concluded that routine endocervical curettage should be a part of pre operative assessment of an abnormal pap test but it may be unnecessary in the evaluation for residual dysplasia.(12)

Olaniyan B meta analysis explained the validity of colposcopy in the diagnosis of precancerous lesions. He concluded that colposcopy is one of the valid tools for the diagnosis of precancerous lesions.(23)

Jin h,Wan Y *et al*, evaluated that new cytologic screening methods on preinvasive lesions.They are pap smear,liquid based cytology and computer technology .They concluded that woman ranging from 30 – 50 years should do cytologic screening and colposcopic examination regularly.(16)

Basu P.S and Sankaranarayanan *et al*, studied the findings of VIA and VILI in cervical cancer screening. They concluded the sensitivity of VIA and VIAM test were 55.7% and 60.7% respectively .(3)

Etherington used video telecolposcopy to record the colposcopy findings.The findings subsequently transmitted to a specialist for interpretation. The sensitivity for this was 88.9% and the specificity was 93.3%.(11)

Yarandi and colleagues studied the colposcopic and biopsy findings of woman with cytologic diagnosis of ASCUS. They concluded that ASCUS was a good indicator for detecting SIL and condyloma.(37)

Benedict J.L did an analysis on 84,244 patients by cytology and colposcopy program in British Columbia .He found that colposcopy correlated well with cytology within one degree in 90% of cases. The cytology and histology correlation seen is 82%.(4)

ACOG concluded that the conventional pap smear was responsible for the initial success in reducing the incidence of cancer cervix. But it had broad range of sensitivity of 30 - 87% and it had more false negative rate of 14 – 33%.

In 2004, Camille Andy showed that the pap smear had the sensitivity of 51% due to high false negative rates.(5)

In 2005,Longatto Filho A *et al* study showed that conventional pap smear had the sensitivity of 59% and specificity of 97.8%.LBC showed the sensitivity of 33.3% and specificity of 100%.(18)

In 2006,Williams A R concluded that after introduction of liquid based cytology , unsatisfactory smear rates were reduced.Dyskaryosis rates were improved.This add significant benefits to colposcopy.(36)

Donald Angstetra *et al* study (2009) LBC and conventional pap smear showed higher sensitivity for high grade lesions.The unsatisfactory rates were lower for LBC.(8)

B.M.Van Hemel *et al* study proved that the Turbitec cytocentrifuge method as a good LBC method(35).

In 2010, Pimple .S.A *et al* study concluded that colposcopy is the best screening tool for CIN detection.(25)

In 2012, Shuchi consul *et al* study concluded that the combination of pap smear,VIA and VILI had 100% sensitivity in detecting precancerous lesions(32)

CERVICAL INTRAEPITHELIAL NEOPLASIA (CIN)

DEFINITION

CIN means disordered arrangement of abnormal cells of stratified squamous epithelium in all the layers,but the basement membrane is intact.

DEVELOPMENT

- The existence of preinvasive stage in the development of cancer cervix has been known Sir Johns Williams in harvein lectures in 1886.
- In 1910, Rubin *et al.,* described the non invasive changes at the margins of invasive carcinoma. He introduced the term carcinoma *in situ*.
- Improvements in cytological techniques lead to the identification of early precursor lesions called dysplasia, a name that acknowledges the malignant potential of these preinvasive lesions.
- The carcinoma *in- situ* lesion was treated very aggressively, where as dysplasias were believed to be less significant and were treated or not treated colposcopic biopsy and cryosurgery.
- The precancerous lesions have the potential to become cancer cervix after long duration if they not treated earlier.
- The term CIN was introduced by Richardt in 1968. He suggested that displasias have the potential for progression.

- Most of the CIN 1and some CIN 2 lesions regress spontaneously without treatment. Untreated high grade CIN lesions may progress to invasive carcinoma.

- Proliferating metaplasia without mitotic activity should not be called dysplasia or CIN because it does not progress to invasive cancer.

- Proliferating metaplasia with mitotic activity progress to invasive cancer and they are called as dysplasias or CIN lesions.

TRANSFORMATION ZONE

- The cervix has two portions, one is endocervix which is lined by columnar epithelium, and the other one is ectocervix which is lined by squamous epithelium.

- The junction between the epithelium is called as squamo columnar junction.

- The area between the original old and new squamo columnar junction is called as transformation zone.

ETIOLOGY

CIN is most likely to start either during menarche or after pregnancy, because during that time metaplasia is most active.

But after menopause women have only little metaplasia and they have only minimal risk of developing CIN due to human papilloma virus infection.

In 1995, the WHO's International Agency for Research on Cancer convened consensus panel to examine the evidence implicating specific sexually transmitted types of HPV in the causation of cervical neoplasia.

Extensive molecular biologic and epidemiologic research confirms certain HPV types are causative factors for cervical cancer in humans.

Human papilloma virus infection is a trigger factor in origin of cancer cervix.

Some 13 types of Human papilloma virus were identified as high risk oncogenic viruses (types 16, 18, 31, 33 etc..).Types 16,18 are responsible for more than 90% of precancerous lesions and more than 70% of cancers.

Human papilloma virus 16 is the most common HPV type universally detected with increased frequency in high-grade intraepithelial lesions and invasive cancers.

HPV16 is associated with 50% of cervical squamous cell carcinoma and 30% of adenocarcinomas.

HPV16 infection is not very specific to cause cervical cancer in humans. HPV16 infection can be found in 16% of women with low grade lesions and in upto 14% of women with normal cytology.

HPV 18 infection is found in 23% of women with invasive cancers, 5% of women with CIN2/3 5% of women with CIN1 and 2% of women with negative findings. So HPV 18 infection is more specific.

RISK FACTORS

I. Demographic factors

- ✓ Older age,
- ✓ Race (e.g Black, Hispanic, American Indian),
- ✓ Residence in selected parts of Africa, Asia or Latin America
- ✓ Low socio-economic status.
- ✓ Lower education status.

II. Behavioral and sexual factors

- ✓ Sexual promisquity,
- ✓ Early sexual exposure,
- ✓ Cigarette smokers,
- ✓ Long term oral contraceptive use,
- ✓ Diet low in folate, carotene, vitamin C.

III. Medical/Gynecologic factors

- ✓ Multiparity,
- ✓ Early age at first pregnancy,
- ✓ History of sexually transmitted disease (especially herpes genitalis or HPV associated lesions) infection with specific type of HPV,
- ✓ Lack of routine cytologic screening
- ✓ Immunosuppression (any case).

TYPES OF CIN

1. CIN1

It refers to the cellular changes confined to the lower one third of the Epithelium. It corresponds to mild dysplasia.

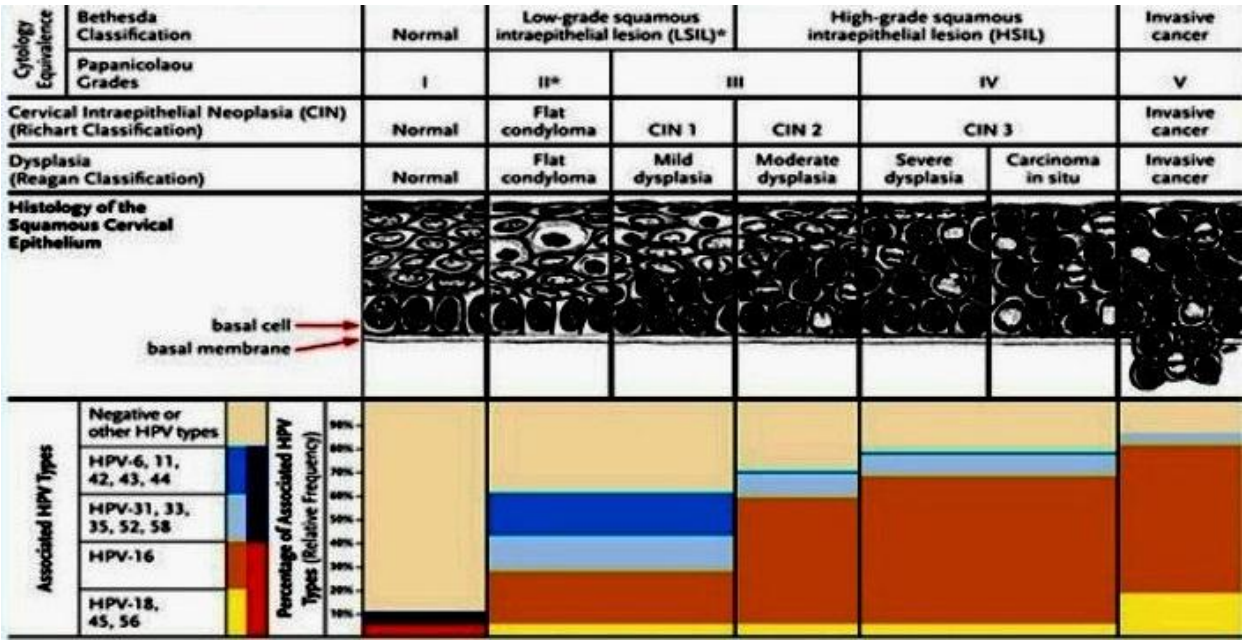
2. CIN2

It refers to the cellular changes confined to the lower two thirds of the Epithelium. It corresponds to moderate dysplasia.

3. CIN3

It refers to the cellular changes confined to the entire Epithelium. It includes both severe dysplasia and carcinoma *in situ.*

CLASSIFICATION



PROGRESSION AND REGRESSION

Progression and regression occurs due to various factors. Progression occurs due to continous exposure to high risk HPV infection, low immunity and poor hygiene. Regression is due to host natural and acquired immunity.

Progressive and Regressive changes in CIN lesions:

- Most of the CIN lesions spontaneously regress without treatment.
- Most of CIN1 lesions will regress within a year or two. Some CIN 1 lesions will progress to cervical carcinoma *in-situ* and rarely progress to invasive cancer.
- In CIN 2 lesions, half of them will regress within two years without treatment. 5% of lesions will progress to invasive carcinoma.
- In CIN 3 lesions, progress to invasive carcinoma is more compared to CIN1and2.

CHANGES	CIN 1 (%)	CIN 2 (%)	CIN 3 (%)
Regression	50 – 60	41 – 43	33
Persistance	30 - 41	40 – 48	55
Progression to CIN 3	10 – 19	9 – 20	Not Applicable
Progression to Squamous cell carcinoma	± 1	5	≥ 12

SCREENING

- CIN lesions mostly have no symptoms. So it is essential for the women must have regular cervical screening to detect preinvasive lesion.
- Cervical screening is a way of checking women regularly for changes in the cells in the cervix to identify cervical lesions in precancerous stage.
- Invasive cervical cancer is mostly preventable if the precancerous lesions are detected early by effective screening methods and treated with best methods.
- Several screening methods are now easily available for early detection of precancerous lesions.
- The exposure to carcinogens starts from the onset of sexual activity, so screening starts at this time.
- Screening methods vary from country to country and region to region.

ACOG GUIDELINES FOR SCREENING

- Initial screening - age 21years or 3 years after vaginal sex
- Interval - Every year for either liquid – based Pap smear or conventional pap smear.

  Every 2-3 years after age of 30 with 3 consecutive smears are normal.
- Discontinue - No upper limit of age.

VARIOUS SCREENING METHODS

1	Conventional Pap smear
2	Bimanual pelvic Examination
3	Visual inspection of cervix after applying Lugol's iodine (VILI)
4	Visual inspection of cervix after applying 5% acetic acid (VIA)
5	Colposcopic VIA, VILI.
6	Colposcopic directed biopsy
7	Liquid based cytology
8	Automated cervical screening techniques
9	Neuromedical system
10	HPV DNA testing
11	Polar probe test
12	Laser induced fluorescence
13	Speculoscopy
14	Cervicography

COLPOSCOPY

- ✓ Colposcopy is one of the medical diagnostic procedures to examine the cervix vulva, vagina under high magnification and bright illumination.
- ✓ It is used to detect precancerous and cancerous lesions of cervix, vagina, and vulva.
- ✓ Whenever cervical screening test is positive, irrespective of the method used or when the patient complaints of post coital bleeding, persistent vaginal discharge next most important step is colposcopy.
- ✓ KOLPOS-vagina, SKOPOS-look at.

AIMS OF COLPOSCOPY

1. To determine the position of Transformation Zone
2. To confirm or refuse the suspicious of cervical intra epithelial lesion.
3. To recognize or rule out invasive cancer or glandular disease of the cervix.
4. To facilitate treatment.
5. Monitor progressive or regressive changes of cervical intra epithelial lesions1, 2.
6. Follow up of treatment procedures like cryotherapy, LLETZ, other ablative and excisional procedures.

PROCEDURE

- The most important part of the colposcopic examination is identifying the transformation zone and identifying normal and abnormal areas.

- The procedure must be explained and informed to the patient and consent to be obtained.
- Insert the bivalve cusco's speculum and examine the cervix – after exposing the cervix, assess the secretion of the cervix, the obvious examination findings like ectopy, nabothian follicle, condyloma, ulcer etc., are noted.
- First apply normal saline either with the spray or with soaked cotton ball and remove the excess mucus and discharge.
- Then identify the proximal and distal borders of the transformation zone.
- Then use green filter and examine the blood vessel patterns
- The new squamo columnar junction may be seen using a Q-Tip applicator and try to see the anterior of posterior lip that helps to visualize the Squamo-columnar junction.
- An endocervical speculum or the tips of the long dissection forceps is used to visualize the Squamo-columnar junction.If the squamo-columnar junction is not seen entirely,it is called as "Unsatisfactory" colposcopy.
- The distal limit of the transformation zone namely the original old squamo-columnar junction is identified by finding the most distal crypt opening or nabothian follicles in the lips of cervix and drawing an imaginary line connecting these land marks.

- Applying 3 to 5% acetic acid: Then 3 to 5% acetic acid is applied and the appearances of acetowhite areas are noted. The areas where there is increased keratin and nuclear protein, example immature squamous metaplasia, inflammation, condyloma, precancerous areas pick up acetic acid. Abnormal areas pickup the acetic acid faster and retains it for a longer time. The acetowhite is denser in precancerous and cancerous areas. In immature squamous metaplasia it is less pale, thin and often translucent and with illdefined borders.

- Applying Lugol's Iodine: Normal squamous epithelium stains mahogany brown with Lugol's Iodine due to glycogen .The coloumnar epithelium does not contain glycogen and does not stain with iodine. Likewise immature squamous metaplasia, inflammatory epithelium and congenital transformation zone do not contain glycogen and do not or partially stained with Iodine.

- The next step is to integrate the findings of saline, acetic acid and Iodine test to make an assessment. IFCPC nomenclature and swede scoring systems are used for interpretation.

- Take biopsy if necessary

- Inspect the vaginal walls, vulva and perineum when the speculum is withdrawn.

- Interpret the findings.

INTERPRETATION

First step in colposcopy is complete visualization of new Squamo-columnar junction and when new Squamo-columnar junction is not fully visible the examination is judged unsatisfactory.

1. Normal colposcopic findings.
2. Abnormal colposcopic findings.
3. Colposcopic findings suggestive of invasive cancer.
4. Unsatisfactory colposcopy.
5. Other findings like,

a) Condylomata,

b) Keratosis,

c) Ectopy,

d) Inflammation,

e) Trophy,

f) Deciduosis of pregnancy,

g) Polyps.

IFCPC

Accepted in Rio world congress, July 5, 2011

Nomenclature committee chairman Jacob Borstein MD

2011 IFCPC colposcopic terminology of the cervix	
General assessment	Adequate/inadequate for the reason - (i.e., cervix obscured by inflammation, bleeding, scar)

		Squamo-columnar junction visibility completely visible, partially visible, not visible. Transformation zone type 1, 2, and 3.	
Normal colposcopic findings		Original squamous epithelium: Mature Atrophic Columnar epithelium: Ectopy Metaplastic squamous epithelium: Nabothian cysts. Crypt (gland) openings Deciduosis in pregnancy.	
Abnormal colposcopic findings	General Principle	Location of the lesion: Inside or outside the T – zone Location of the lesion by clock position. Size of the lesion: Number of cervical quadrants the lesions covers, Size of the lesion in percentage of cervix.	
	Grade 1 (Minor)	Thin aceto-white epithelium Irregular, geographic border	Fine mosaic Fine punctuation.
	Grade 2 (Major)	Dense aceto-white epithelium, Rapid appearance of aceto-whitening, Cuffed crypt (gland) openings	Coarse mosaic, Coarse punctuation, Sharp border, Inner border sign, Ridge sign.
	Non Specific	Leukoplakia (keratosis, hyperkeratosis), erosion. Lugol's staining (Schiller's test) Stained/Non-stained.	
Suspicious for invasion		Atypical vessels. Additional signs: Fragile vessels,Irregular surfaces,Exophytic lesion,Necrosis,Ulceration (necrotic), tumor/gross neoplasm.	
Miscellaneous findings		Congenital transformation	Stenosis,

	zone Condyloma Polyp (Ectocervical) Endocervical Inflammation.	Congenital anomaly, Post treatment consequences, Endometriosis.

SWEDE SCORING SYSTEM

SCORE	0	1	3
ACETO UPTAKE	0 or Transparent	Thin, milky	Distinct, stearin
MARGINS	0 or diffuse	Sharp but irregular Jagged, satellites	Sharp & even Difference in level
VESSELS	Fine, regular	0	Coarse or atypical Vessels
LESIONS SIZE	< 5 mm	5-15 mm or 2 Quadrant	>15mm,3-4 quadrants or endocervically Undefined.
IODINE UPTAKE	Brown	Faintly or patchy Yellow	Distinctly yellow
A total score < 5 or 0 for aceto or margins excluded high grade lesion.			

DIFFICULT SITUATIONS IN COLPOSCOPY

Infections of the cervix and vagina are very common in the reproductive age group and cause many problems and it also obscures the colposcopic features of the transformation zone.

1. There is sloughing of the superficial epithelium resulting in red blotches and resemble preinvasive lesion.

2. Acetowhite areas sometimes may not be as obvious due to thickening of the superficial epithelium and sloughing of the epithelium.

3. The tissue is easily traumatized during examination and may bleed.

4. Basal layers of the epithelium are not well glycogenated, so there is patchy up take of iodine resulting in a leopard skin appearance due to infection.

5. Recurrent ulceration and healing by fibrosis can result in distortion of the cervix and misinterpretation of findings.

6. Specific infections like herpes can produce large coalesced ulcer that look like invasive cancer.

DIFFERENCE BETWEEN INFLAMATION AND CIN

1. Usually infections are symptomatic and precancerous lesions mostly asymtomatic.

2. The changes are spread diffusely over the cervix and not strictly confined to the transformation zone.

3. Inflammatory punctuations are fine with minimal inner capillary distance and possible extension to the vagina.

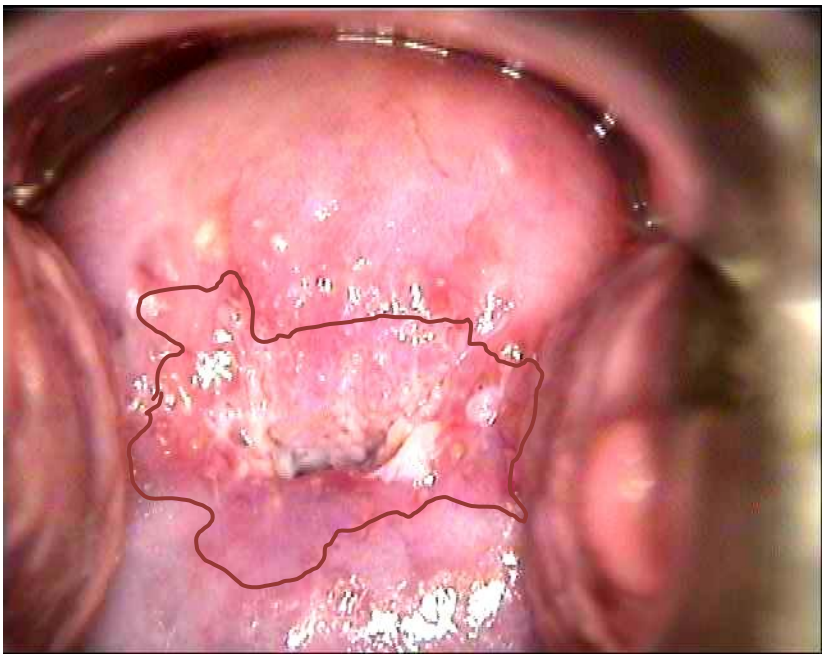
ADVANTAGES

- ✓ This test is exactly localize the lesion.
- ✓ It evaluates the extension of lesion.
- ✓ It differentiates inflammatory and cancer lesions.
- ✓ It differentiates invasive and non invasive cancer lesions.
- ✓ Follow up is easy.

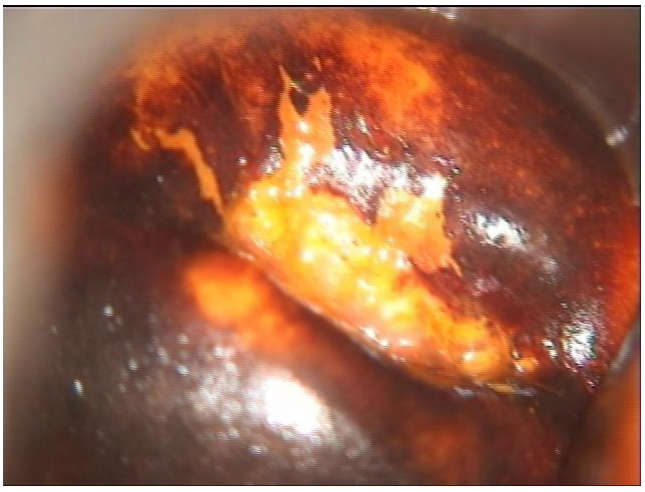
DISADVANTAGES

- ✓ Unable to detect endocervical lesion.
- ✓ Needs more training and experience.

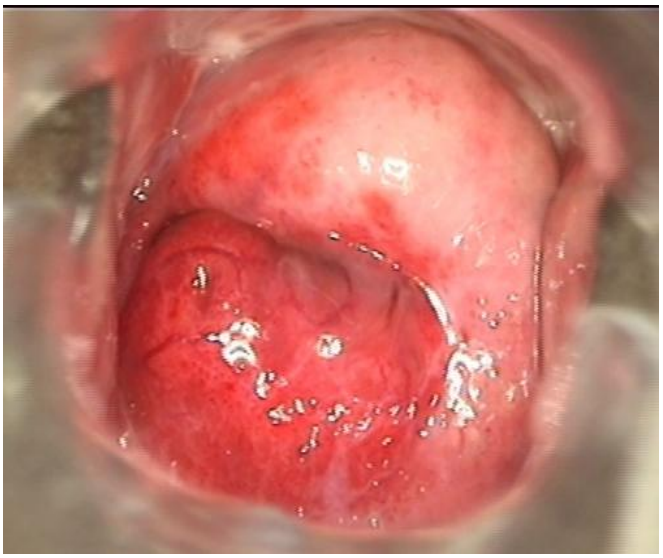
NORMAL CERVIX

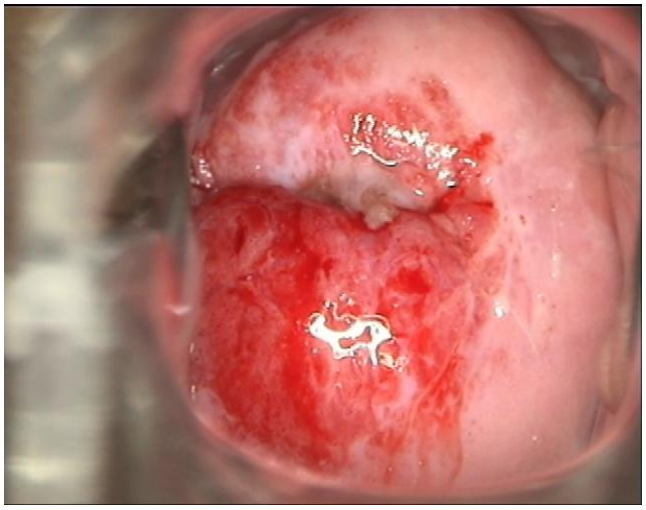


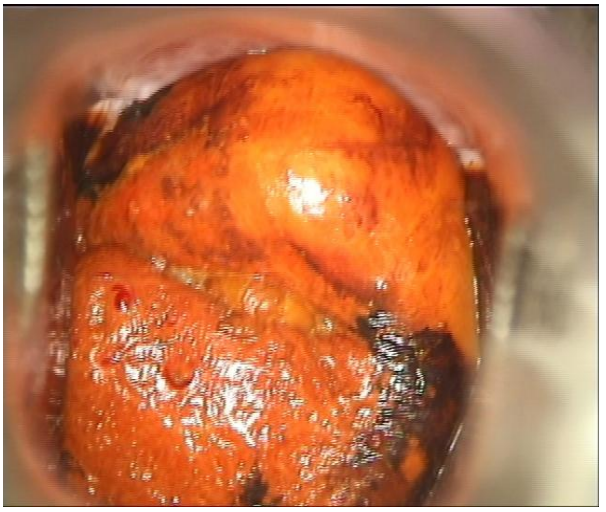
LOW GRADE LESION



HIGH GRADE LESION







PAP SMEAR

DEFINITION

Pap smear is a cytological screening test used to detect precancer and cancer lesions in the cervix Transformation zone. Pap smear was invented by Greek doctor Georgios Papanicolaou.

The pap smear test has been used since 1950 as a screening test and effectively reduced the incidence.

INDICATIONS

Screening guidelines for Pap smear vary from country to country. Screening starts at 20years or 25years and continues until 60years of age.

Screening is typically recommended every three to five years if previous Pap smear results are normal.

If age 65years with previous history of normal pap tests no further tests are needed.

TYPES

(i) Conventional Pap smear.

(ii) Liquid based cytology.

PREPARTION METHOD OF CONVENTIONAL PAPSMEAR

Cusco's bivalve speculum is used to open the vaginal wall and allows access to the cervix.

The ectocervix is scraped circumferentially using a spatula. The cytobrush is recommended for sampling the endocervical cells. Endocervical brush produces highest yield of endocervical cells. Both these samples best represent the cervical disease status.

Women planning to have a pap test for cervical cancer are advised to avoid the test during their menstrual period .They are advised to avoid douching, sexual intercourse, putting tampons or medications into the vagina for 48 hours prior to the screening test.

The basis for these recommendations is to obtain the most representative cellular sample and to avoid false negative samples.

Both douching and tampons use are risk factors for removing the most superficial cells, that represent the area where a precancerous lesion is most likely to occur.

Ectocervix samples are obtained before endocervical samples to reduce the effect of bleeding from the endocervix.

PROCEDURE

- The patient is placed in dorsal position and adequate light source is used to visualize vagina and cervix.
- A cusco's bivalve speculum is used to expose the cervix. No lubricant should be used on the bivalve speculum.
- Ayre's spatula is placed over the ectocervix with the longer protrusion in the cervical canal and rotates the spatula for 360 degree over the

ectocervix. This would help in scraping the cells from the entire transformation zone.

- If it appears to be inadequate, the spatula must be rotated for several times.
- The sample cells from the spatula are placed onto the glass slide by rotating the spatula against the glass slide in a clockwise manner.
- Next, an endocervical brush is placed inside the endocervix and rotated firmly against the canal and an endocervical sample is taken, which is placed on the same slide.
- The slide is immediately fixed to avoid air-drying using 95% ethyl alcohol and send the slides to pathology laboratory.

RISK FOR ABNORMAL PAP SMEAR

- Women who begin sexual activity before age of 18,
- Women who have history of multiple sexual partners,
- Women who have repeated sexually transmitted diseases,
- Women who have smoking habits,
- Women who become pregnant before age of 18.

ADVANTAGES

- It is cost effective and also inexpensive
- It is ideal for mass screening.
- It can be done by para medical staff.
- It is also used for detection of endocervical lesion.
- It is also used for detection of adenocarcinoma.

DISADVANTAGES

- It has low sensitivity
- The value of single test is limited.
- It cannot localize the lesion.

LIQUID BASED CYTOLOGY PAP SMEAR

Liquid based, thin layer cytotechnology was developed to address the limitation of pap smear. LBC is used to improve the specimen accuracy of Pap smear.

METHODOLOGY

Thin prep method:

- ❖ Thin prep (cytyc) samples are collected from the cervix by using special cervical cytobrush, a broom like device.
- ❖ The device is inserted over the endocervical canal until the shorter bristles contact the ectocervix.

- It is rotated over the cervix five times in one direction to obtain the sample.
- The cytobrush is removed from the cervix. Decap the broom and then put it in to the bottom of the vial that contains preservative solution.
- In the preservative solution, the bristles are spread apart and release the sample. Finally the broom is swirled vigorously to further release material to the preservative solution and then the broom is discarded.

LABORATORY PROCEDURE

- The vials are placed on the thin prep processor machines, and a hollow cylinder with a 20 mm diameter filter bonded to its lower surface is inserted into the vial.
- After a rotatory motion to disperse loose cell clusters and mucin, a vacuum is applied to the cylinder and cells are trapped on to the filter.
- The cylinder is then inverted 180 degrees and the filter is gently pressed onto glass slide, which transfer the cells from filter to slide.
- The slide is then fixed and stained. This techniques result in a monolayer of cells on the slide, which can be read more quickly than conventional cytology.
- Liquid based cytology is less likely to be affected by blood than conventional Pap smear, but should not be recommended to obtain it during menstruation.

ADVANTAGES

- It removes mucus, blood and other specimen contamination.
- LBC method transfers 80-90% of cells to the slide as compared to 10-20% with conventional tests.
- Cells are distributed uniformly.
- This method improves fixation.
- Preserves cellular architecture.
- It has shorter screening time.
- It has lower unsatisfactory rate.
- Greater sensitivity for CIN lesions.
- Automation.
- Increased diagnosis of ASCUS & LSIL.

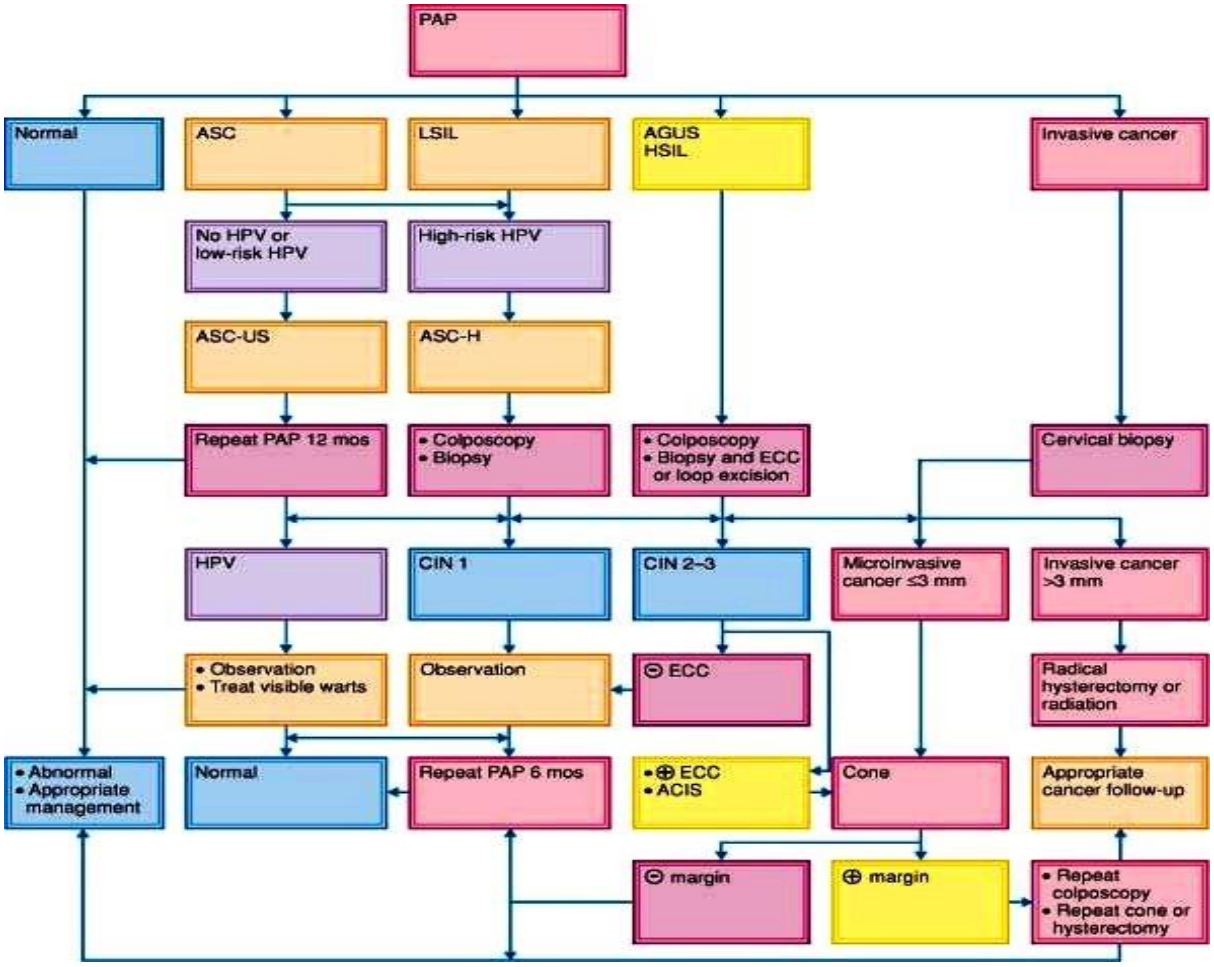
DISADVANTAGES

- Cost of transport vials, equipments and processing is more
- Less specificity
- Reduced reporting of invasive carcinoma

COMPARISON OF PAPANICOLAOU, WHO AND BETHESDA SYSTEM

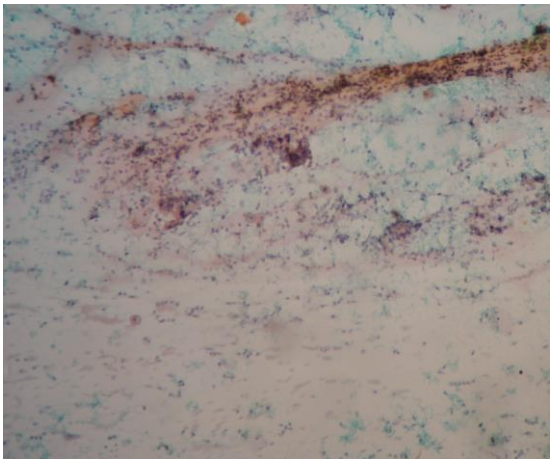
Papanicolaou	WHO system	Bethesda System
Class I	Normal	Within normal limits
Class II	Atypical	Benign cellular changes or Atypical squamous cells of undetermined significance
Class III	Dysplasia Mild dysplasia Moderate dysplasia Severe dysplasia	Squamous epithelial cell abnormality Low Grade squamous intra epithelial lesions (SIL) High grade SIL High grade SIL
Class IV	Carcinoma *in situ*	High grade SIL
Class V	Invasive squamous cell carcinoma Adeno carcinoma	Squamous cell carcinoma Adenocarcinoma

MANGEMENT OF CIN LESION ACCORDING TO PAP SMEAR

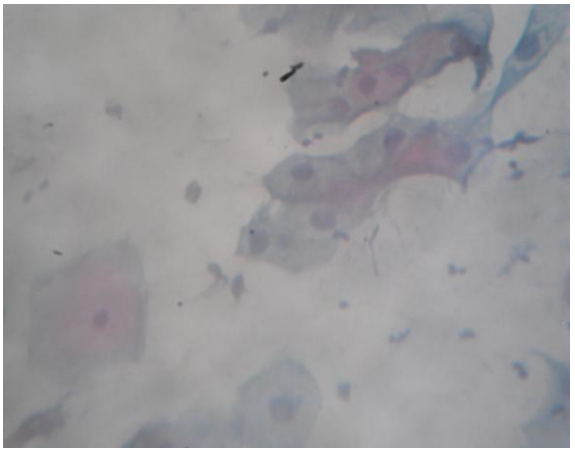


PAP SMEAR

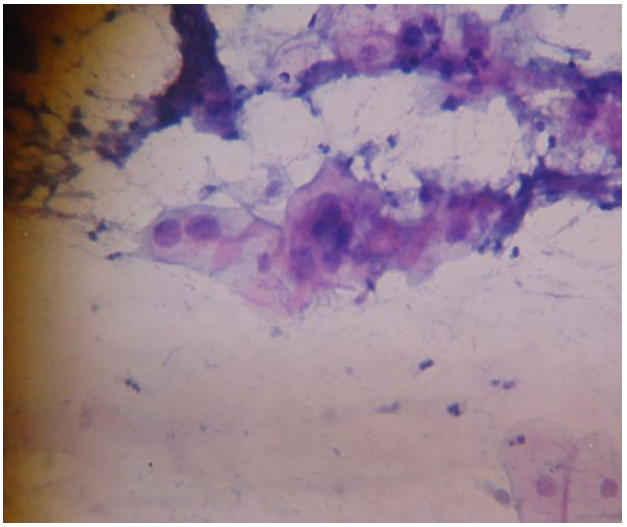
NIL



LSIL

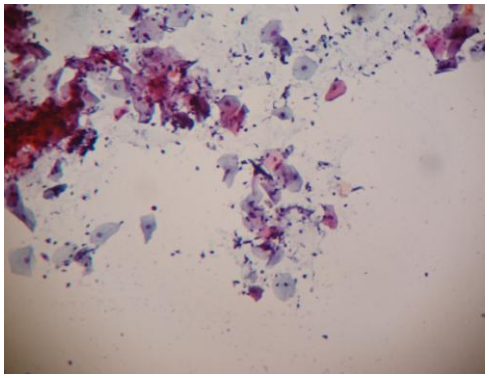


HSIL

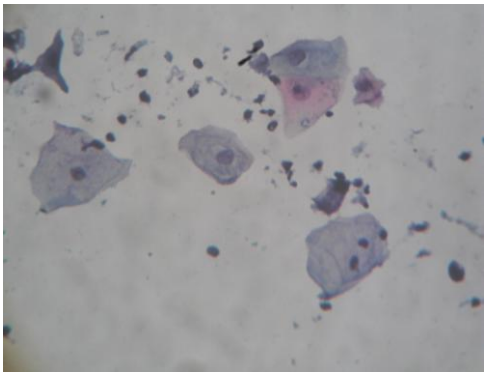


LIQUID BASED CYTOLOGY

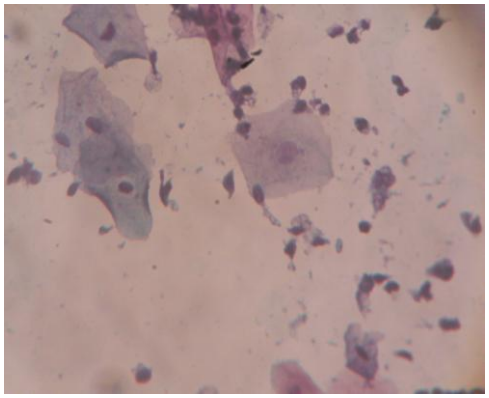
NIL



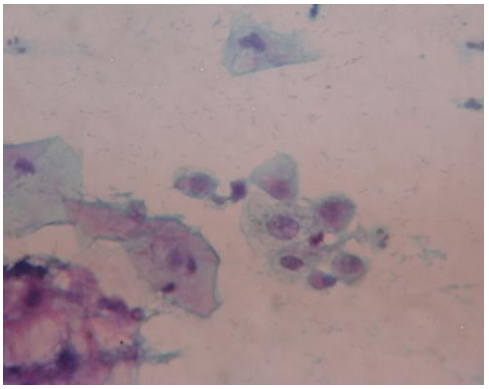
ASCUS



LSIL



HSIL



AUTOMATED SCREENING TECHNOLOGY

- Automated screening techniques perform quality control rescreening.
- This method is used for primary screening of cervical smears.
- The Auto pap 300 and PAPNET (Neuromedical systems) are the two methods available for cervical screening.
- These methods depend on neural network technology are used for identification of abnormal cervical cells.
- The Autopap 300 method is approved by the USFDA for primary and secondary cervical screening.
- The PAPNET is approved for secondary screening.

BIMANUAL PELVIC EXAMINATION

- It includes inspection of external genitalia and insert speculum and examine the vagina and cervix.
- Feel the cervix, uterus and adnexa with gloved fingers and put the other hand over the lower abdomen.

HPV-DNA TESTING

- HPV-DNA testing using hybrid capture2 is the most sensitive test.It is superior to either cytology smear or colposcopic examination.
- In new algorithm HPV-DNA test is a primary screening test.
- It had higher sensitivity and specificity than others.
- PCR assay is the commonest test.
- It is helpful to women more than 30 years of age.
- It is also used for ASCUS evaluation.
- In high and medium resource settings after this test only pap and LBC done.

VIA (Visual inspection of the cervix with acetic acid)

- This method is simple and easy to perform
- It is freely available in all government settings.
- It is done by paramedical staff in health camps, outpatient clinics etc.
- It is done by visualization of the cervix after applying acetic acid.
- Cervix is inspected after 2 minutes.
- Lesions which stain acetowhite are positive. Unstained areas are called as negative.
- Dull white, semi transparent areas are low grade VIA.
- Dense or oyster whites with sharp borders are high grade VIA.
- Positive cases are reffered to higher centres for expert opinion, follow up and treatment.

VILI (Visual Inspection with Lugol's Iodine)

- VILI is one of the visual method to screen the cancer cervix in low resource settings.
- This method is also simple and easy to perform.
- It is freely available in all government settings.
- It is done by paramedical staff in health camps, outpatient clinics etc.
- It is done by visualization of the cervix after applying 50% lugol's iodine solution.
- Cervix is inspected after application.
- Normal vaginal and cervical squamous epithelium contain glycogen and stains as mahogany brown.
- Normal columnar epithelium, immature and abnormal epithelium have no glycogen not stained by iodine solution and appeared as mustard yellow.
- Positive cases are reffered to higher centres for expert opinion,follow up and treatment.

SPECULOSCOPY

- This is also one of the screening method
- Inspection of the cervix after the application of 5% acetic acid .
- Examine the cervix with chemiluminiscent light .
- Low power magnification is used.
- It is not used routinely .

CERVICOGRAPHY

- First bimanual pelvic examination and Pap smear collection are done routinely.
- Acetic acid is applied to the cervix.
- It involves taking photographs of the cervix using a special camera .
- The photographs are then developed.
- The slide is projected on a 2X2 meter screen.
- It is read by an expert in colposcopy.

POLAR PROBE

- It is one of the screening methods.
- This technology is based upon the fact that the tissue impedance to electrical simulation differs between normal and abnormal tissues.
- The investigators have tried to utilize spectral and electrical stimulation of the cervical tissues.
- It is used as an adjunct to conventional Pap smear testing.

LASER INDUCED FLUORESCENCE

- It is used as a screening procedure.
- Low power laser illumination can induce endogenous tissue fluorescence. This depends upon the chemical and morphological composition of individual tissues of the patient.
- The spectroscopic difference is used to differentiate normal tissues.

COMPUTER IMAGING

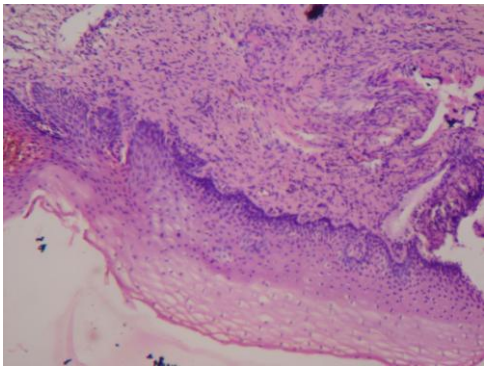
- The diagnosis of precancerous changes is primarily a task of visual discrimination and sorting of graphical information.
- A lot of focus on the use of computers to assist this process.
- This is very similar to cervico-graphic techniques .
- In this technique the computer replaces the colposcopy expert.

COLPOSCOPIC DIRECTED BIOPSY

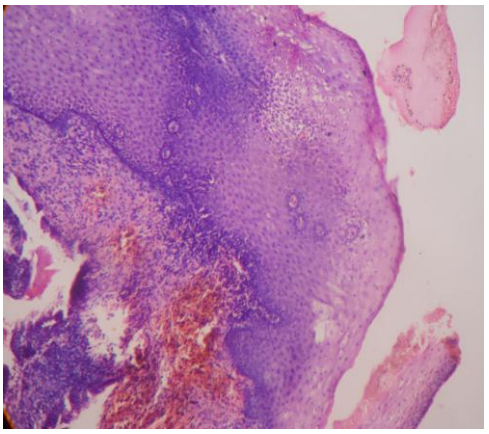
- It is the best method for detecting cervical cancer and precancerous lesions.
- Cervix is first examined with colposcopy and abnormal areas are localized.
- The abnormal areas are biopsied by using cervical punch biopsy forceps.
- This is confirmatory method and gold standard.

BIOPSY

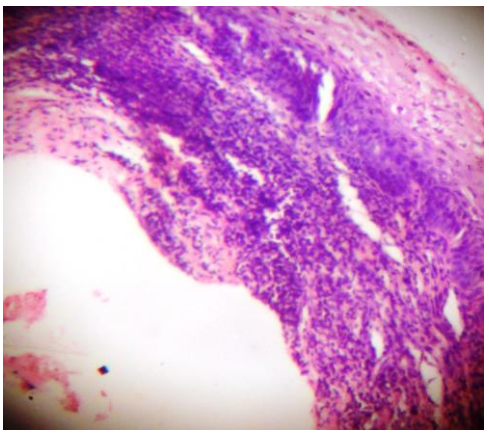
CERVICITIS



CIN 1



CIN 2



PREVENTION

VACCINATION

- HPV infection is necessary for the development of cervical cancer, the primary was the development of a prophylactic vaccine to protect against HPV infection.
- The development of a prophylactic vaccination became possible through the development of protein mimics that simulate the outer most protein capsid of the virus ie virus like particles (VLP).
- Gardasil is a quadrivalent vaccine containing the VLPs for HPV 6,11,16,18 was approved by the USFDA in 2006.
- Cervarix is a bivalent vaccine contains VLPs for 16, 18 were approved in 2009.
- Both bivalent and quadrivalent vaccines are highly effective in preventing CIN2, CIN3, adenocarcinoma in situ caused by HPV16,18in women from 15-26 of years age.
- The women who are sero-negative and HPV DNA negative for HPV16 and 18 at vaccination and received all the three vaccinations the efficacy is 100%. This protection is documented to last as long as 6.4 years after vaccination.
- HPV 6, 11 infections that cause genital warts is prevented by quadrivalent vaccine.
- Routine HPV vaccination is recommended for female children at 11 to 12 years of age, but it may be provided as early as 9 years and as latest as 18 years.
- Screening practices for cervical intra epithelial neoplasia and cancer should remain unchanged in both vaccinated and unvaccinated women.

CONDOM USE

ABSTINENCE

TREATMENT OF CIN

- The diagnosis of cervical intraepithelial neoplasia is confirmed before starting the treatment. In many developing countries the treatment is offered at the first colposcopic clinic visit.

- **In ASCUS group**

    - Three methods used: Colposcopy, HPV-DNA testing and repeat cytology

    - If HPV - DNA is negative repeat cytology after 12 months.

    - If HPV-DNA is positive for high risk type, immediate colposcopy is done.

    - If colposcopy showed CIN lesion or cancer treat the patient as per guidelines.

- **In ASC-H group**

    - Colposcopy is done immediately . If colposcopic examination shows CIN lesion or cancer treat the patient as per guidelines.

    - If colposcopic examination shows negative findings, repeated cytology is done at 6 & 12 months.

- **In LSIL group**
    - Immediate colposcopic examination is done.
    - If colposcopy showed CIN lesions or cancer treat the patient as per guidelines.
    - If colposcopy showed no lesion, cytology is done at 6 & 12 months or HPV-DNA testing done at 12 months.
- **In HSIL group**
    - Women with HSIL have significant risk of CIN 2, 3 and invasive cancer.
    - Immediate colposcopic examination is done.
    - Complete review of the cytology and biopsies are taken.
    - If the results are unchanged, the patient should undergo excisional method of treatment.
    - Women with unsatisfactory colposcopy also undergo excisional method of treatment.
- **Normal colposcopy findings**

  They are advised to undergo repeat screening examination after 3-5 years.

- **Reproductive tract infection**

  The women with reproductive tract infections should be treated according to WHO guidelines.

- **Leukoplakia**

  In leukoplakia ,the area should be biopsied and submitted for HPE to rule out cervical cancer and treat according to the HPE findings.

- **Condyloma**

  In condylomata , the area should be biopsied and localized ectocervical exophytic lesions may be treated with either ablative method or excisional method of treatment.

- **In CIN1 lesions,**

  - Most CIN1 lesions are regressed spontaneously without treatment.
  - Repeat cytology at 6 & 12 months or HPV-DNA testing at 12 months are done.
  - Follow-up with colposcopy and cytology at 12 months are done.
  - If the lesions persist or progress diagnostic excisional treatment is done.
  - Non complaint patients should have immediate treatment.

- **In CIN 2/3 lesions,**
    - The risk of persistence and progress to invasive cancer is more in CIN 2/3 lesions.
    - In CIN 2/3 lesions immediate treatment with excisional method of treatment.
    - In excisional treatment, if the margins have lesions then follow-up with colposcopy and endocervical curettage.
    - If follow-up shows persistence and patient completed the family hysterectomy is the best option.

INVASIVE CANCER

- A diagnosis of invasive squamous cell carcinoma or adenocarcinoma may be found during examination.
- It requires prompt referral for definitive treatment with either surgery or radio therapy, with or without chemotherapy.

METHODS OF TREATMENT

- **ABLATIVE METHODS**

  Eradication of abnormal epithelium and prevent its recurrence with least morbidity. This method includes cryosurgery, electrocoagulation diathermy and CO_2 laser ablation.

- **EXCISIONAL METHODS**

  The excision of the transformation zone treats the abnormality and specimen is available for HPE. They are LLETZ, cold-knife conization, CO_2 laser excision, NETZ and hysterectomy.

- **CRYOSURGERY**

  - It is an ablative procedure and an optimal treatment for benign epithelial abnormalities of the cervix.
  - It destroys precancerous tissue through cryonecrosis.
  - Safe method of treatment with no significant morbidity or mortality risks.
  - A rapid freeze followed by a slow thaw is the most damaging to cells especially neoplastic cells. A sequence of two freeze-thaw cycles (freeze-thaw-freeze-thaw) may produce more tissue destruction than a single cycle (freeze for 3 minutes and thaw for 5 minutes)
  - It is the destructive procedure which draws heat from the tissue in contact with the cryoprobes through which a freezing agent, N_2O (-89°C) or CO_2 (-68°C), is circulated converting the tissue into an iceball through ice ball cryoprobes.
  - No sample is obtained for HPE.

- **Eligibility criteria**

- CIN is confirmed by cervical biopsy/colposcopy.
- Entire lesion – located in the ectocervix without extension to the vagina or endocervix.
- Lesion can be covered by the largest available cryotherapy probe (2.5 cm).
- No evidence of invasive cancer.
- Women should not be pregnant.
- If recently delivered, women should be in atleast 3 months post-partum:
    - No evidence of PID.
    - No sample is obtained for HPE.

ELECTROCAUTERY

- It is one of the oldest ablative method.
- The depth of destruction is only 2 to 3 mm.
- Residual lesion always present after treatment.
- No tissue is available for HPE after treatment.

ELECTRO-COAGULATION DIATHERMY

- This method includes deep coagulation of cervical stroma with needle electrodes and destruction with ball electrodes. It is one of the ablative methods.
- Healing occurs in 4 weeks.

CO_2 LASER VAPORIZATION

- This method uses high intensity beam produces tissue vaporization and boiling of intracellular water and explosion of cell.
- Incineration of protein and mineral and charring of the treated area.
- Depth of tissue destruction is 6-7mm.
- Rapid healing occurs with minimal fibrosis.

LLETZ (Large Loop Excision of Transformation Zone)

- It is the most commonly used excisional method of treatment.
- It offers more than 95% of cure rate and is a simple and safe procedure.
- It can be done as an out-patient method of treatment.
- It is done under local anesthesia. It is done in the large majority of CIN lesions.
- It is the procedure of choice in CIN 2/3 lesions with satisfactory colposcopy.

- **Method**
  - Radio frequency electric current is used for a large loop excision of the transformation zone.
  - It can be done with colposcopic guidance.
  - Different sizes of loops are available depend upon the site and size of the lesion.
  - Usually the specimen is removed in a single pass, sometimes it needs multiple passes.
- **Advantages**
  - Specimen is available for histopathological examination.
  - It can be done as an out-patient method of treatment.
  - It is done under local anesthesia.
- **Complications**
  - Intra and post operative haemorrhage.
  - Cervical stenosis after the procedure.
  - Increased pre term delivery and PPROM (due to deep excisions).
- **Follow-up**
  - Avoid vaginal douches, tampons and coitus for one month.
  - Profuse and sometimes blood stained discharge may persist for two weeks.
  - Follow-up at one year with colposcopy.
  - If the lesions persist, biopsies are taken.
  - Repeat LLETZ can be done if lesions persist.

NEEDLE EXCISION OF THE TRANSFORMATION ZONE (NETZ)

- It was invented in an attempt to combine the ease of loop excision with the surgical accuracy of cold knife conisation.
- A needle electrode is used for the procedure.
- It is one of the excisional methods of treatment.

COLD KNIFE CONE BIOPSY

- It is used for micro invasive cancer where evaluation of margin is important.
- It is done under local anesthesia.
- The incision should be made posteriorly and then carried anteriorly.
- The depth of destruction is 15-20mm.
- If cone margin is +ve - 22% residual lesion is present.
- If cone margin is –ve - 4% residual lesion is present.
- The complications are haemorrhage, sepsis, infertility and stenosis.

HYSTERECTOMY

This procedure includes Removal of uterus with cervix

INDICATIONS

- Associated with other gynecological Conditions.
- Persistent Abnormal pap Smear Following Excision or Ablative Procedure.
- Positive Endocervical margin after Conisation treatment.

MATERIALS AND METHODS

A study was conducted in the Dept of Obstretics and Gynaecology at Institue of Social Obstretics and Government Kasthurba Gandhi Hospital, Triplicane, Chennai-5 during the year 2011-2012.

This study was conducted in 100 women, who fulfilled the selection criteria. The average number of women attending ISO & KGH was about 100 to 150 per day in Gynecology clinic.

Among them women who fulfilled the selection criteria were randomly selected.

INCLUSION CRITERIA

- All women in the reproductive age group.

EXCLUSION CRITERIA

- Pregnancy,
- History of Hysterectomy,
- History of cervical treatment for CIN,
- IUCD user,
- Sexual Intercourse with spermicidal jelly, douches/tampons 24hrs prior to pap smear examination.

MATERIALS

1. **Colposcope:** It is the simple colposcope with magnifications of 5X, 10X and 20X with inbuilt green filter was used. The magnification can be altered by changing the power of the eyepieces.

The magnifications of 7.5X - 10X were preferred which was excellent for localizing or zooming in the area of interest and for examining the vascular architecture. The best focal distance was between 250 mm and 300mm. This allowed easy working and manipulation of instruments without hampering the vision

2. Basic colposcope tray containing

- Cotton swabs with small cotton tipped applicators,
- 5ml syringes for spraying,
- Cusco's bivalve speculum,
- Normal saline(0.9% NaCl),
- Freshly prepared 5% acetic acid,
- Lugol's Iodine,
- Ayre's spatula with endocervical brush,
- Cervical cytobrush,
- Liquid prep preservative solution,
- Glass slide,
- 95% ethanol solution in pap smear jar,
- Cervical punch biopsy forceps,
- 10% formalin for biopsy,
- Monsel's solution,

3. Light microscope

Methods - Basic steps of examination include

❖ Written informed consent and counseling regarding the procedure

- History taking
- Physical examination in general
- Local examination of vulva and perenium
- Speculum examination of cervix and vagina without cream
- Pap smear, LBC - By using cervical cytobrush, both smears are taken
- Normal saline Colposcopy
- Examination through green filter.
- Freshly prepared 5% acetic acid is applied over the cervix.
- Staining the cervix with Lugol's iodine
- Colposcopic directed biopsy using a cervical punch biopsy forceps
- Application of Monsel's paste for hemostasis.
- Interpret the findings using IFCPC nomenclature.
- Patient was positioned in the dorsal lithotomy position.
- Cusco's Bivalve speculum was introduced without use of any lubricant.

A cervical smear was taken with cytobrush placed in os and rotate it 5 times over squamo columnar junction and spread on a glass slide then fixed immediately in 95% Alcohol, then decap the brush and put it into the thin prep preservative solution and sent for cytological analysis.

4. Colposcopic examination of unstained cervix

Cervix was examined under good illumination after cleaning the vagina and cervix with cotton swabs dipped in normal saline in order to remove the discharge.

5. Inspection with green filter

Vascular pattern of cervix appeared in green background when visualized through green filter.

6. Inspection of cervix after 5% acetic acid application

Acetic acid is a mucolytic; After application, changes the colour of cervix after an interval of 10-30 secs. The effect was transitory and faded away in 30-40 seconds. Repeated applications were required throughout the procedure. The speed with which the colour appeared and the speed with which it disappeared was indicative of the degree of underlying lesion. Low grade CIN lesions showed a shiny white, translucent appearance, whereas High grade usually appeared opaque or oyster white. The whole transformation zone must be visualized Surface contour, margin of lesion and appearance of blood vessels are noted.

7. Lugol's iodine application

Cervix was painted with Lugol's iodine in a 50% dilution. Mahogany Brown staining occur in glycogen rich squamous epithelium.The acetowhite area which was stained brown should indicate mature metaplastic epithelium. Mustard yellow or Saffron yellow indicates abnormal lesion. Interpretation of colposcopic findings was done by IFCPC nomenclature and SWEDE Scoring System.

ANALYSIS AND RESULTS

Interpretation of P value

1. If P value is 0.000 to 0.010 then denoted by ** => Significant at 1 % level
2. If P value is 0.011 to 0.050 then denoted by * => Significant at 5 % level
3. If P value is above 0.05 then denote do not put any star or NS => Not Significant at 5 % level

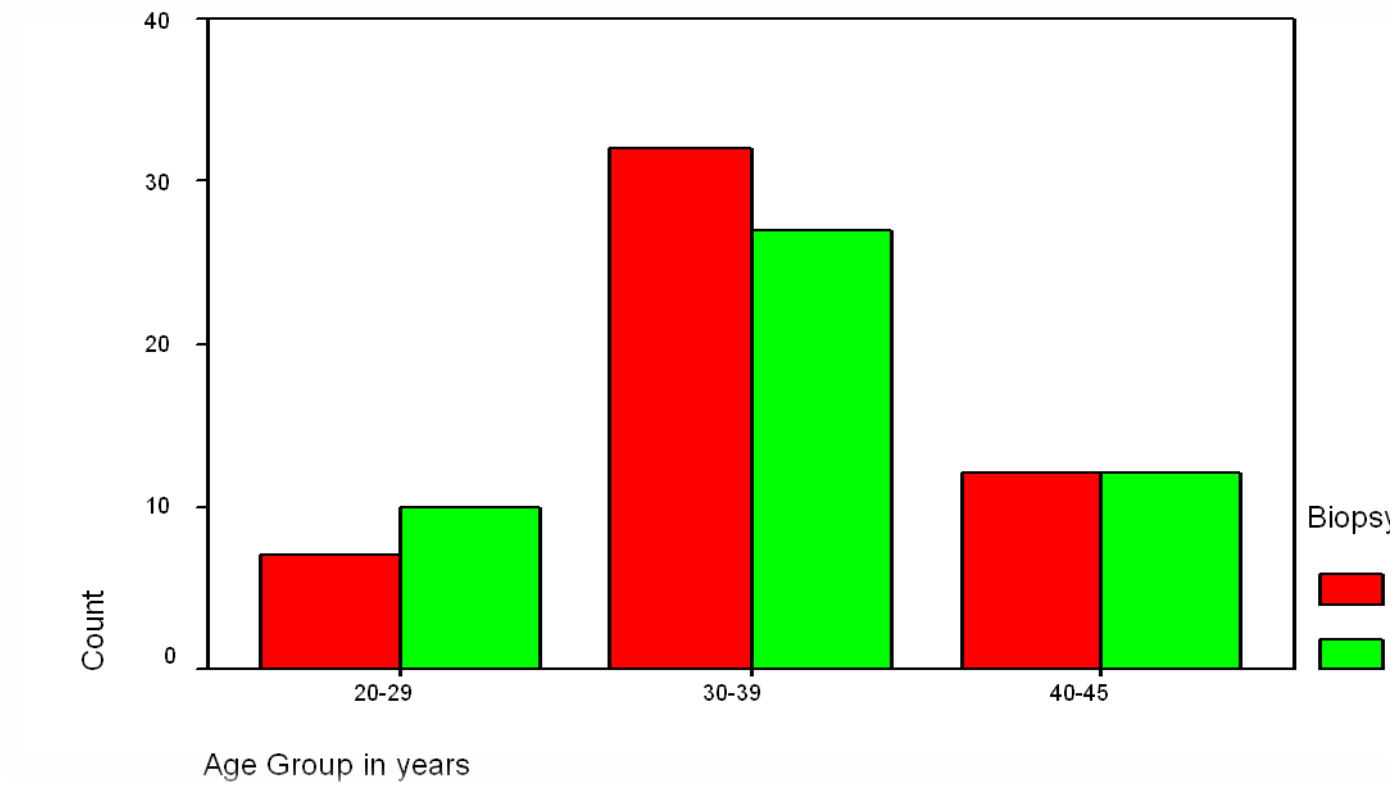
   If the P value is .000 then put <0.001**

AGE GROUP **Table: 1**

Age group in years		Biopsy		Total	Significance (P)
		CIN	Cervicitis		
20-29	Count	7	10	17	0.633
	% within Age Group in years	41.2%	58.8%	100.0%	
	% within Biopsy	13.7%	20.4%	17.0%	
30-39	Count	32	27	59	
	% within Age Group in years	54.2%	45.8%	100.0%	
	% within Biopsy	62.7%	55.1%	59.0%	
40-45	Count	12	12	24	
	% within Age Group in years	50.0%	50.0%	100.0%	
	% within Biopsy	23.5%	24.5%	24.0%	
Total	Count	51	49	100	
	% within Age Group in years	51.0%	49.0%	100.0%	
	% within Biopsy	100.0%	100.0%	100.0%	

Among 100 women, 7 were between 20-29 age group , 32 cases were between 30-39 years and 12 were between 40 to 45 years
Incidence of CIN was 13.7% in 20-29 years age group, 62.7% in 30-39 years age group, 12% in 40 - 45 years age group.
Incidence of CIN was increased in increasing age group. In this study more cases were belongs to 30 – 45 years age group.

Figure: 1



AGE AT MARRIAGE
Table: 2

Age at marriage		Biopsy		Total	Significant(P)
		CIN	Cervicitis		
Upto 19	Count	42	32	74	0.043
	% within Age at marriage	56.8%	43.2%	100.0%	
	% within Biopsy	82.4%	65.3%	74.0%	
20 and above	Count	9	17	26	
	% within Age at marriage	34.6%	65.4%	100.0%	
	% within Biopsy	17.6%	34.7%	26.0%	
Total	Count	51	49	100	
	% within Age at marriage	51.0%	49.0%	100.0%	
	% within Biopsy	100.0%	100.0%	100.0%	

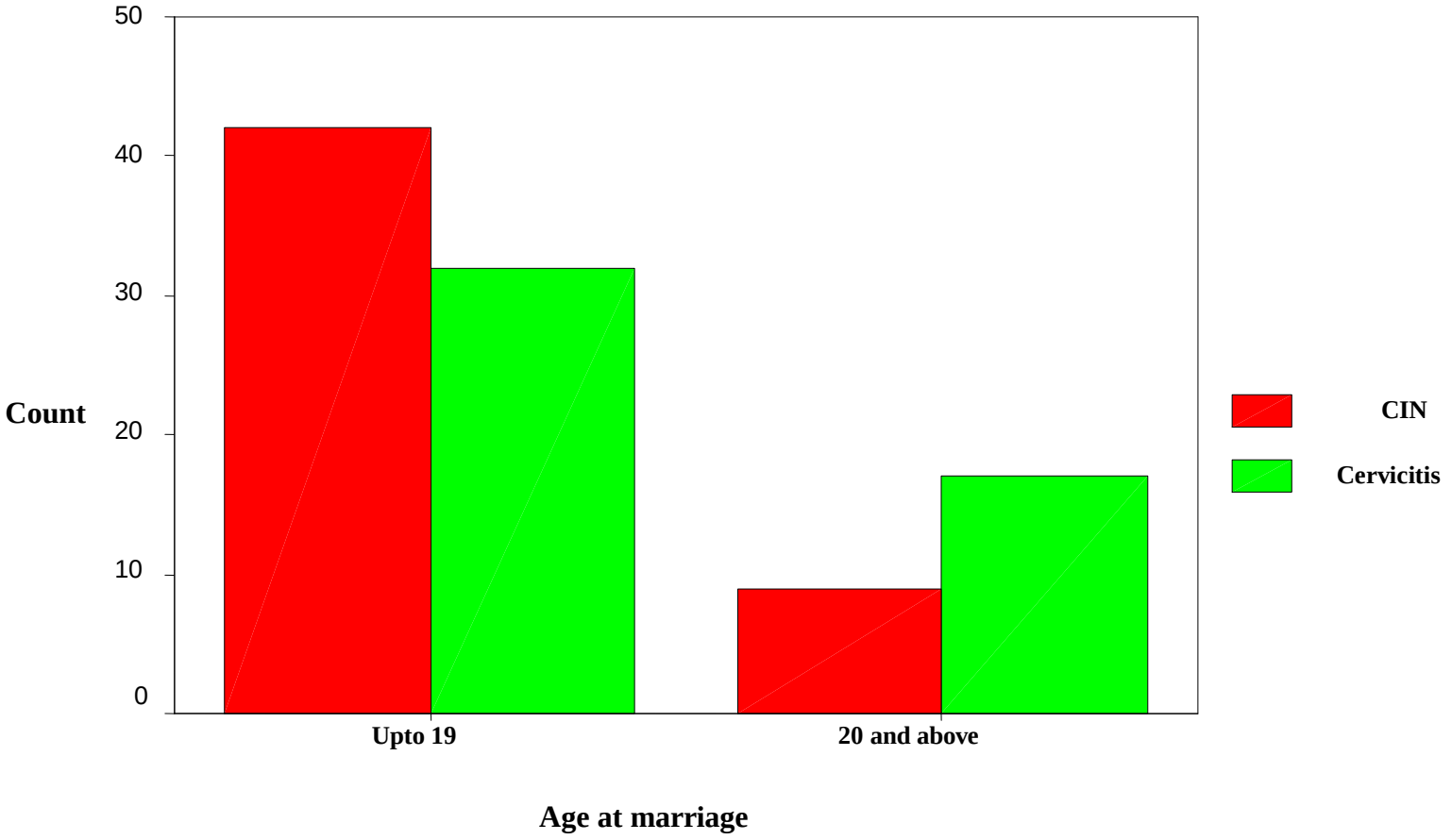
Among 100 women ,74% were married before 19 years and 26 % were married after 20 years.

Incidence increased in early marriage

In this study incidence of CIN was 82.4% in less than 19 years age group and 17.6% in more than 20 years age group.

In this study also incidence of CIN is increased in early marriage.

Figure: 2
Age at Marriage



DURATION OF MARRIAGE

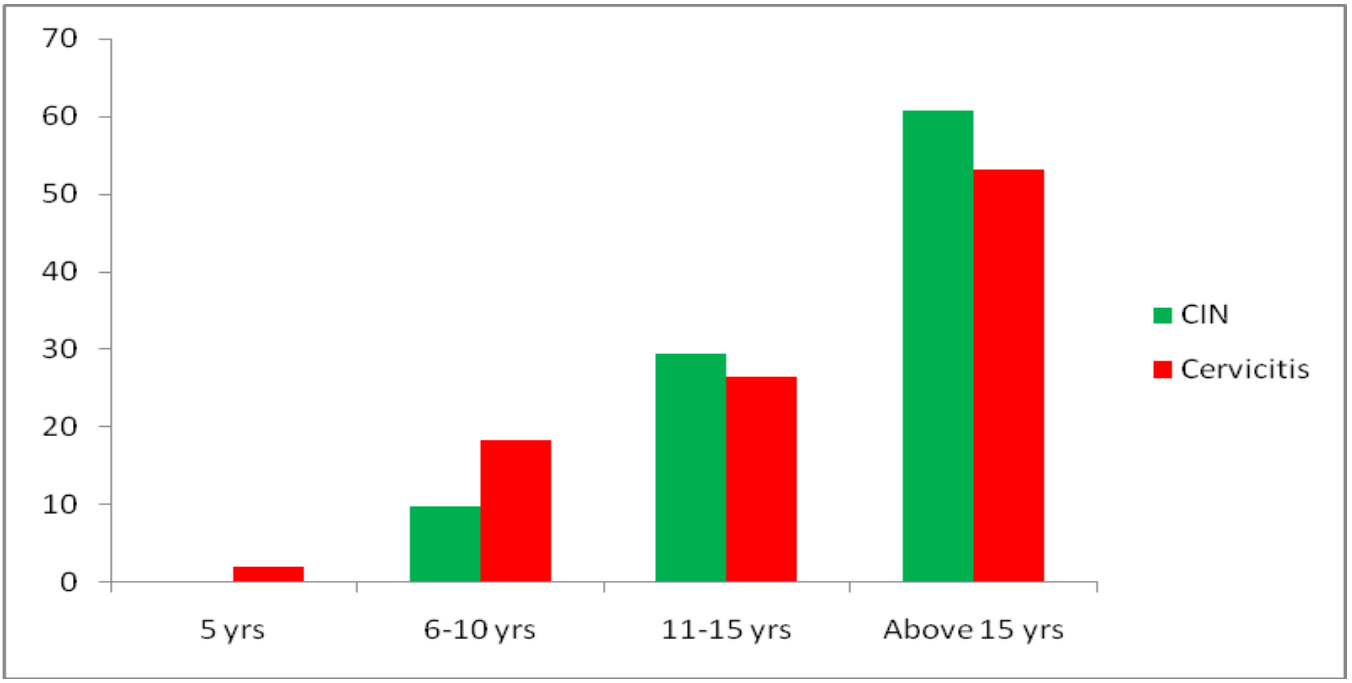
Table: 3

Duration of marriage in years		Biopsy		Total	Significant (P)
		CIN	Cervicitis		
Below 5	Count	0	1	1	0.443
	% within Duration of marriage in years	.0%	100.0%	100.0%	
	% within Biopsy	.0%	2.0%	1.0%	
6-10	Count	5	9	14	
	% within Duration of marriage in years	35.7%	64.3%	100.0%	
	% within Biopsy	9.8%	18.4%	14.0%	
11-15	Count	15	13	28	
	% within Duration of marriage in years	53.6%	46.4%	100.0%	
	% within Biopsy	29.4%	26.5%	28.0%	
Above 15	Count	31	26	57	
	% within Duration of marriage in years	54.4%	45.6%	100.0%	
	% within Biopsy	60.8%	53.1%	57.0%	
Total	Count	51	49	100	
	% within Duration of marriage in years	51.0%	49.0%	100.0%	
	% within Biopsy	100.0%	100.0%	100.0%	

Among 100 women, 1% belongs to below 5 years duration of marriage, 14% belongs to 6 – 10 years duration , 28% belongs to 11 – 15 years and 57% belongs to more than 15 years duration. Incidence increased in long duration of sexual exposure.

In this study CIN lesions 9.8% belongs to 6 – 10 years duration and 29.4% belongs to 11 – 15 years duration and 60.8% belongs to more than 15 years of duration.

Figure: 3
Duration of marriage



SOCIO-ECONOMIC STATUS

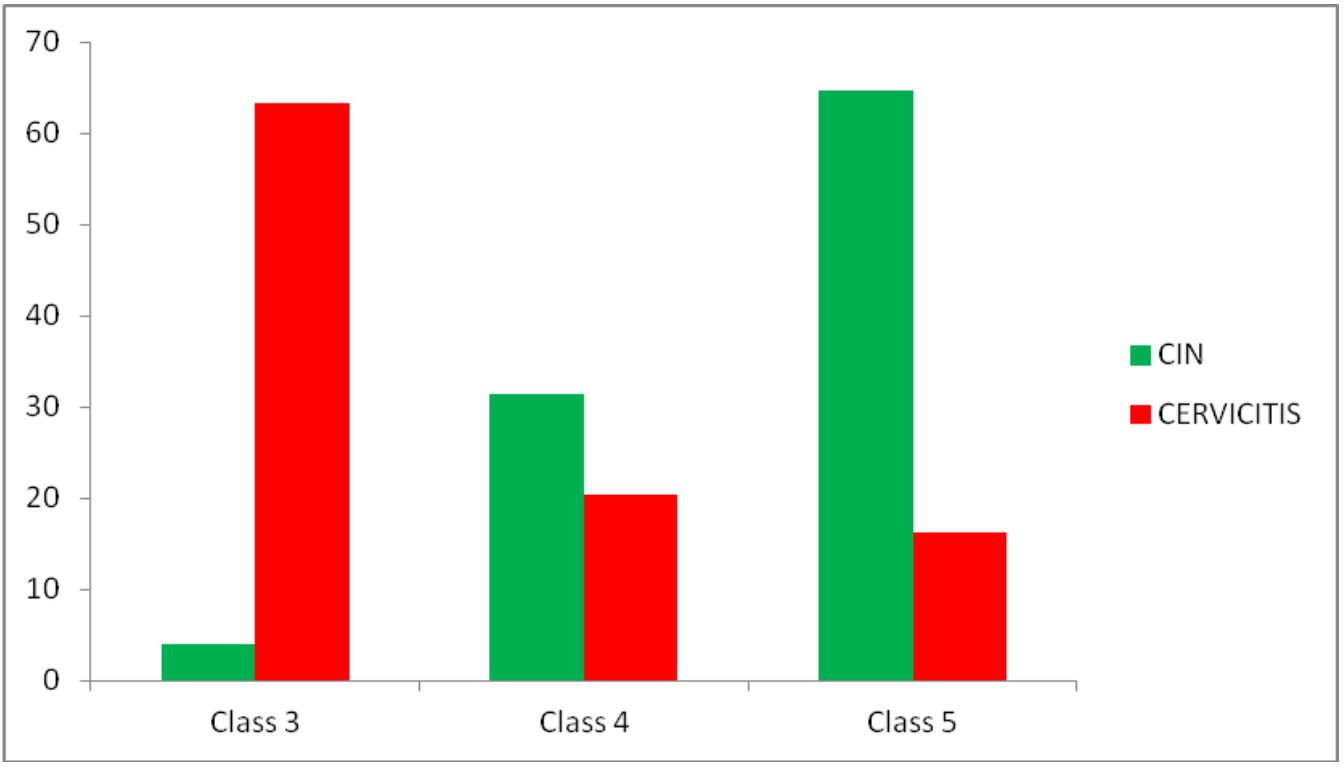
Table: 4

Socio-economic status		Biopsy		Total	Significant(P)
		CIN	Cervicitis		
Class 3	Count	2	31	33	0.000
	% within SES	6.1%	93.9%	100.0%	
	% within Biopsy	3.9%	63.3%	33.0%	
Class 4	Count	16	10	26	
	% within SES	61.5%	38.5%	100.0%	
	% within Biopsy	31.4%	20.4%	26.0%	
Class 5	Count	33	8	41	
	% within SES	80.5%	19.5%	100.0%	
	% within Biopsy	64.7%	16.3%	41.0%	
Total	Count	51	49	100	
	% within SES	51.0%	49.0%	100.0%	
	% within Biopsy	100.0%	100.0%	100.0%	

Among 100 women, 33% of women belongs to class 3, 26% belongs to class 4 and 41% belongs to class 5. CIN lesions more common in lower socio-economic group.

In this study 64.7% CIN lesions belongs to class 5 socio-economic group, 31.4% CIN lesions belongs to class 4 socio-economic group and 3.9% of CIN lesions belongs to class 3 socio-economic group.

Table: 4
Socio-Economic Status



PARITY

Table: 5

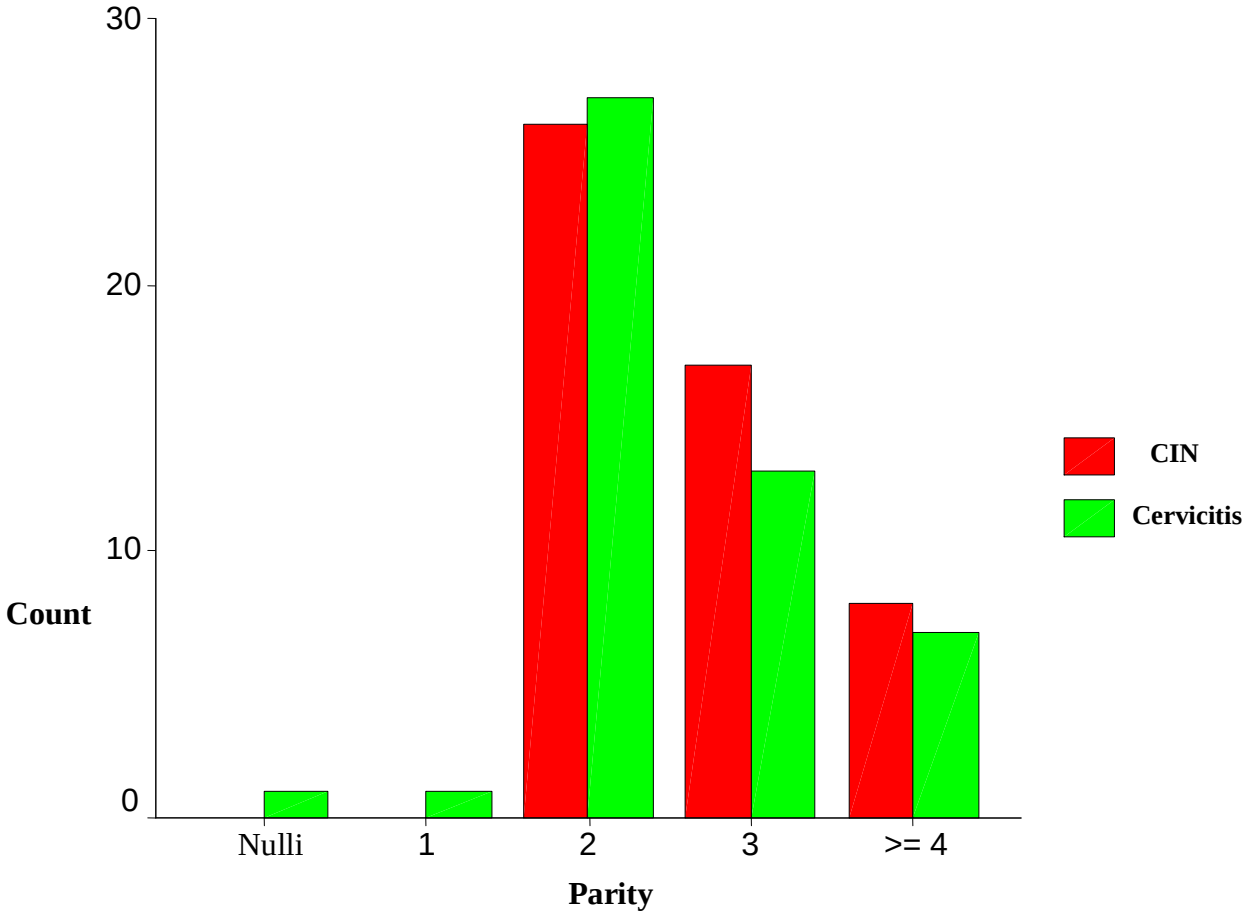
Parity		Biopsy		Total	Significant(P)
		CIN	Cervicitis		
Nulli	Count	0	1	1	0.630
	% within Parity	.0%	100.0%	100.0%	
	% within Biopsy	.0%	2.0%	1.0%	
1	Count	0	1	1	
	% within Parity	.0%	100.0%	100.0%	
	% within Biopsy	.0%	2.0%	1.0%	
2	Count	26	27	53	
	% within Parity	49.1%	50.9%	100.0%	
	% within Biopsy	51.0%	55.1%	53.0%	
3	Count	17	13	30	
	% within Parity	56.7%	43.3%	100.0%	
	% within Biopsy	33.3%	26.5%	30.0%	
>= 4	Count	8	7	15	
	% within Parity	53.3%	46.7%	100.0%	
	% within Biopsy	15.7%	14.3%	15.0%	
Total	Count	51	49	100	
	% within Parity	51.0%	49.0%	100.0%	
	% within Biopsy	100.0%	100.0%	100.0%	

Among 100 women ,1% was nullipara, 1% was primipara, 53% were belonging to para2, 30% were belonging to para3 and 15% were belonging to para4 and above.

Among this CIN incidence was 51% in para 2, 33.3% in para 3, 15.7% in para 4 and above. Among para 3 in 30 cases incidence was 56.7%. Among para 4 and above in 15 cases incidence was 53.3%.

If parity increases occurrence of CIN also increases. In this study also increasing parity had increased incidence.

Table: 5
Parity



LAST CHILD BIRTH
Table: 6

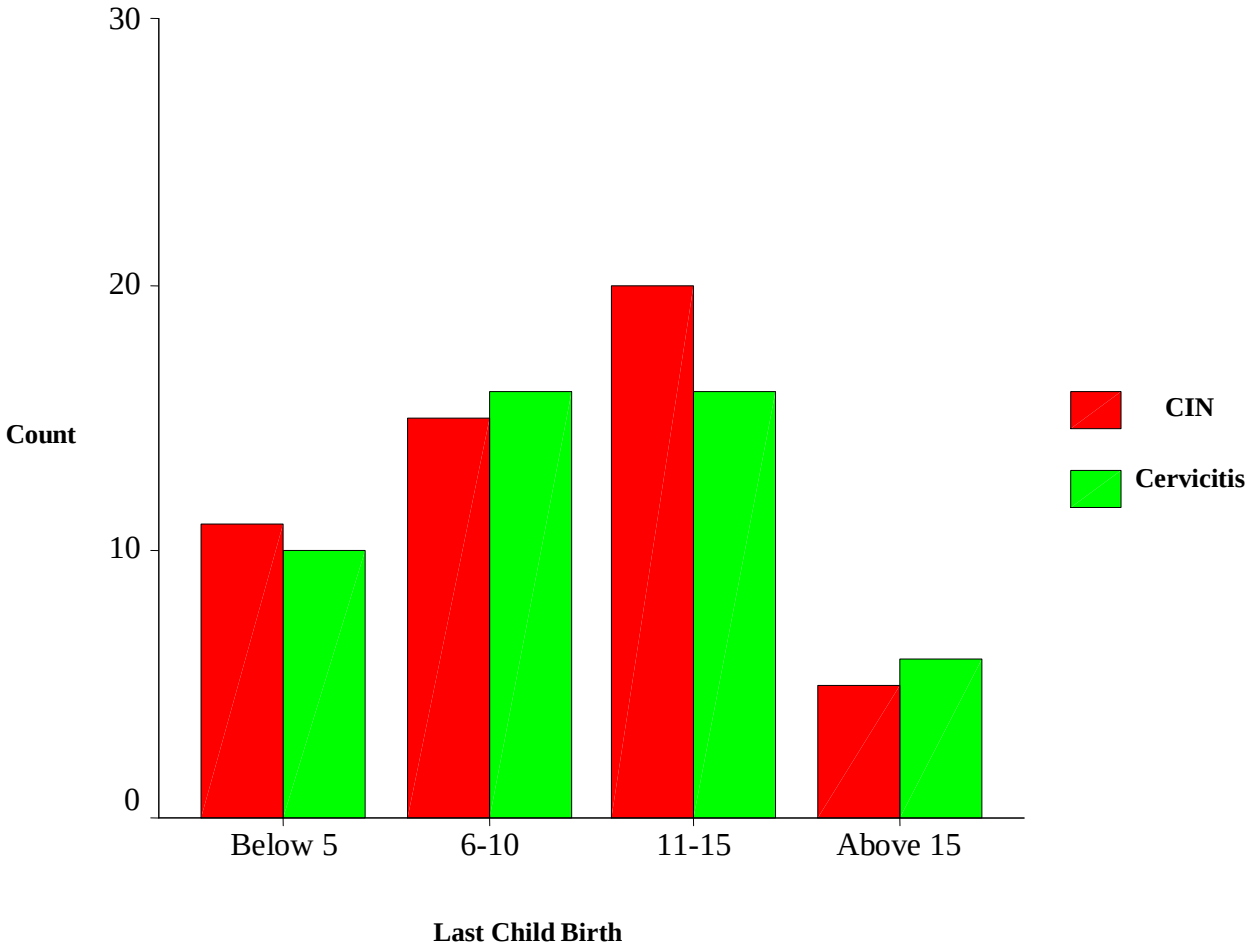
Last Child Birth		Biopsy		Total	Significant(P)
		CIN	Cervicitis		
Below 5	Count	11	10	21	0.913
	% within LCB	52.4%	47.6%	100.0%	
	% within Biopsy	21.6%	20.8%	21.2%	
6-10	Count	15	16	31	
	% within LCB	48.4%	51.6%	100.0%	
	% within Biopsy	29.4%	33.3%	31.3%	
11-15	Count	20	16	36	
	% within LCB	55.6%	44.4%	100.0%	
	% within Biopsy	39.2%	33.3%	36.4%	
Above 15	Count	5	6	11	
	% within LCB	45.5%	54.5%	100.0%	
	% within Biopsy	9.8%	12.5%	11.1%	
Total	Count	51	48	99	
	% within LCB	51.5%	48.5%	100.0%	
	% within Biopsy	100.0%	100.0%	100.0%	

Among 99 women, 21.2% were belonging to LCB 5 years group, 31.3% were belonging to LCB 6-10 years group, 36.4% were belonging LCB 11-15 years group and 11.1% were belonging to LCB more than 15 years group.

Among those incidence of CIN was 21.6% in less than 5 years duration, 29.4% in 6-10 years duration, 39.2% in 11-15 years duration and 9.8% in more than 15 years duration group.

In this study, in 11 - 15 years duration group among 36 cases, 20 cases were CIN ie 55.6% incidence and more than 15 years duration among 11 cases , 5 cases were CIN ie 45.5% incidence .Incidence increases after birth.

Table: 6
Last Child Birth



SYMPTOMS
Table: 7

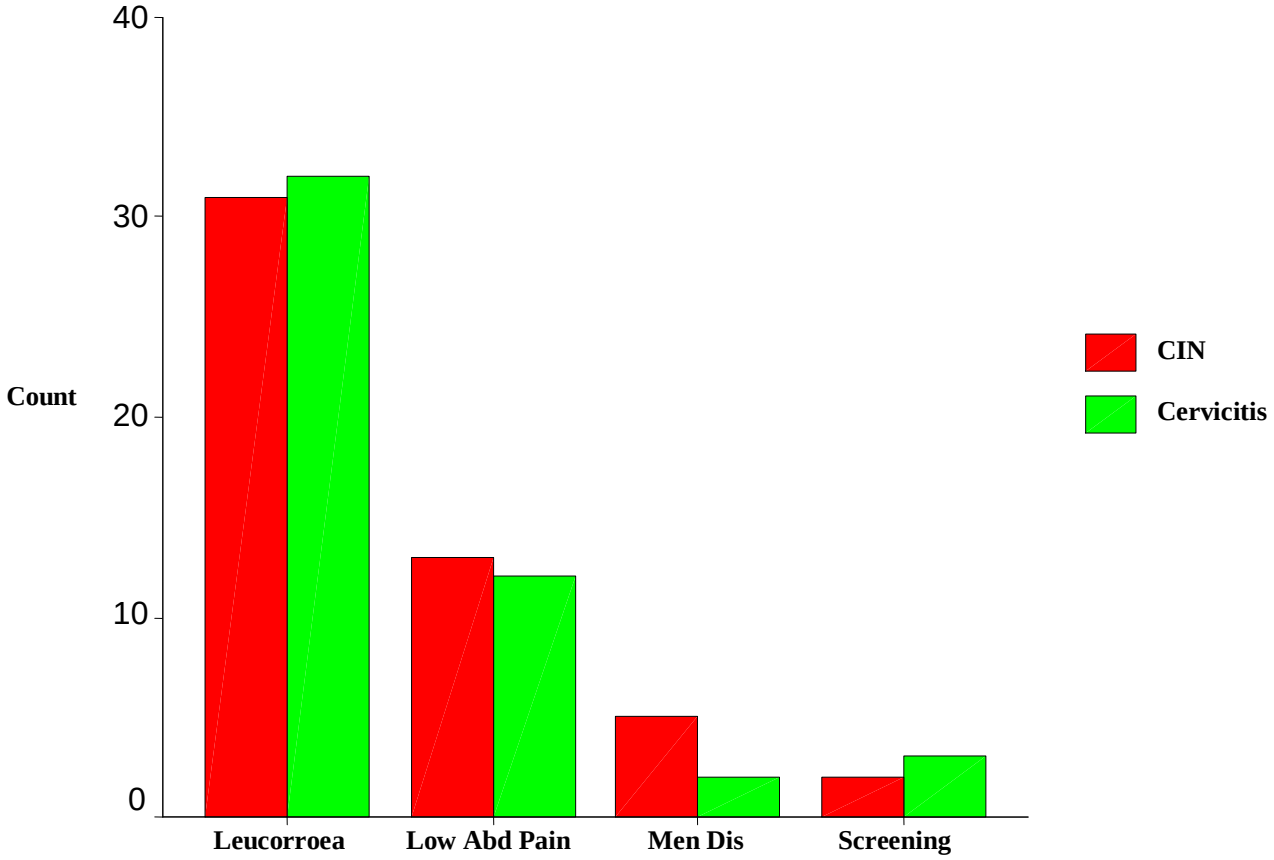
SYMPTOMS		Biopsy		Total	Significant(P)
		CIN	Cervicitis		
Leucorrhoea	Count	31	32	63	0.682
	% within Symptoms	49.2%	50.8%	100.0%	
	% within Biopsy	60.8%	65.3%	63.0%	
Low Abdominal Pain	Count	13	12	25	
	% within Symptoms	52.0%	48.0%	100.0%	
	% within Biopsy	25.5%	24.5%	25.0%	
Men Dis	Count	5	2	7	
	% within Symptoms	71.4%	28.6%	100.0%	
	% within Biopsy	9.8%	4.1%	7.0%	
Screening	Count	2	3	5	
	% within Symptoms	40.0%	60.0%	100.0%	
	% within Biopsy	3.9%	6.1%	5.0%	
Total	Count	51	49	100	
	% within Symptoms	51.0%	49.0%	100.0%	
	% within Biopsy	100.0%	100.0%	100.0%	

Among 100 women, in symptoms wise 63% had come with symptom of Leucorrhoea, 25% had came with symptom of lower abdomen pain, 7% had menstrual disturbances, 5% came for screening for cervical cancer.

Among those CIN incidence was 60.8% in Leucorrhoea group, 25.5% in lower abdomen pain group, 9.8% in menstrual disturbances group, 3.9% in screening group.

In this study more cases belongs to Leucorrhoea group.

Table: 7
Symptoms



EXAMINATION FINDINGS

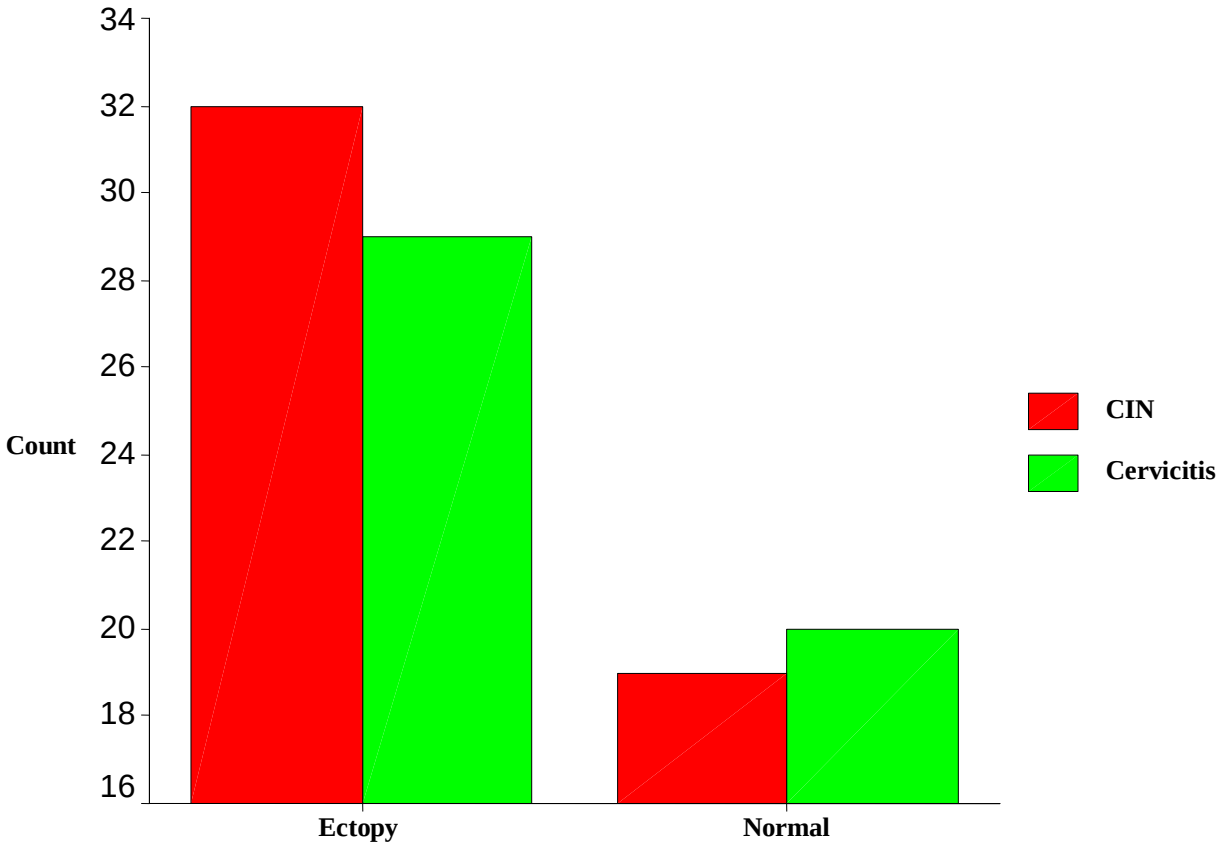
Table: 8

Speculum Examination		Biopsy		Total	Signinficant(P)
		CIN	Cervicitis		
Ectopy	Count	32	29	61	0.436
	% within S/E	52.5%	47.5%	100.0%	
	% within Biopsy	62.7%	59.2%	61.0%	
Normal	Count	19	20	39	
	% within S/E	48.7%	51.3%	100.0%	
	% within Biopsy	37.3%	40.8%	39.0%	
Total	Count	51	49	100	
	% within S/E	51.0%	49.0%	100.0%	
	% within Biopsy	100.0%	100.0%	100.0%	

Among 100 women, 61% of women had ectopy on per speculum examination findings and normal in 39% of patients.

Among 100 women, CIN incidence was 62.7% in ectopy group and 37.3% in normal group.

Table: 8
Speculum Examination



COLPOSCOPY
Table: 9

Colposcopy		Biopsy			Total	Significant(P)
		CIN 1	CIN 2/3	Cervicitis		
High grade lesion	Count	1	11	3	15	0.000
	% within Colposcopy	6.7%	73.3%	20.0%	100.0%	
	% within Biopsy	2.5%	100.0%	6.1%	15.0%	
Low grade lesion	Count	36	0	7	43	
	% within Colposcopy	83.7%	.0%	16.3%	100.0%	
	% within Biopsy	90.0%	.0%	14.3%	43.0%	
Normal study	Count	3	0	39	42	
	% within Colposcopy	7.1%	.0%	92.9%	100.0%	
	% within Biopsy	7.5%	.0%	79.6%	42.0%	
Total	Count	40	11	49	100	
	% within Colposcopy	40.0%	11.0%	49.0%	100.0%	
	% within Biopsy	100.0%	100.0%	100.0%	100.0%	

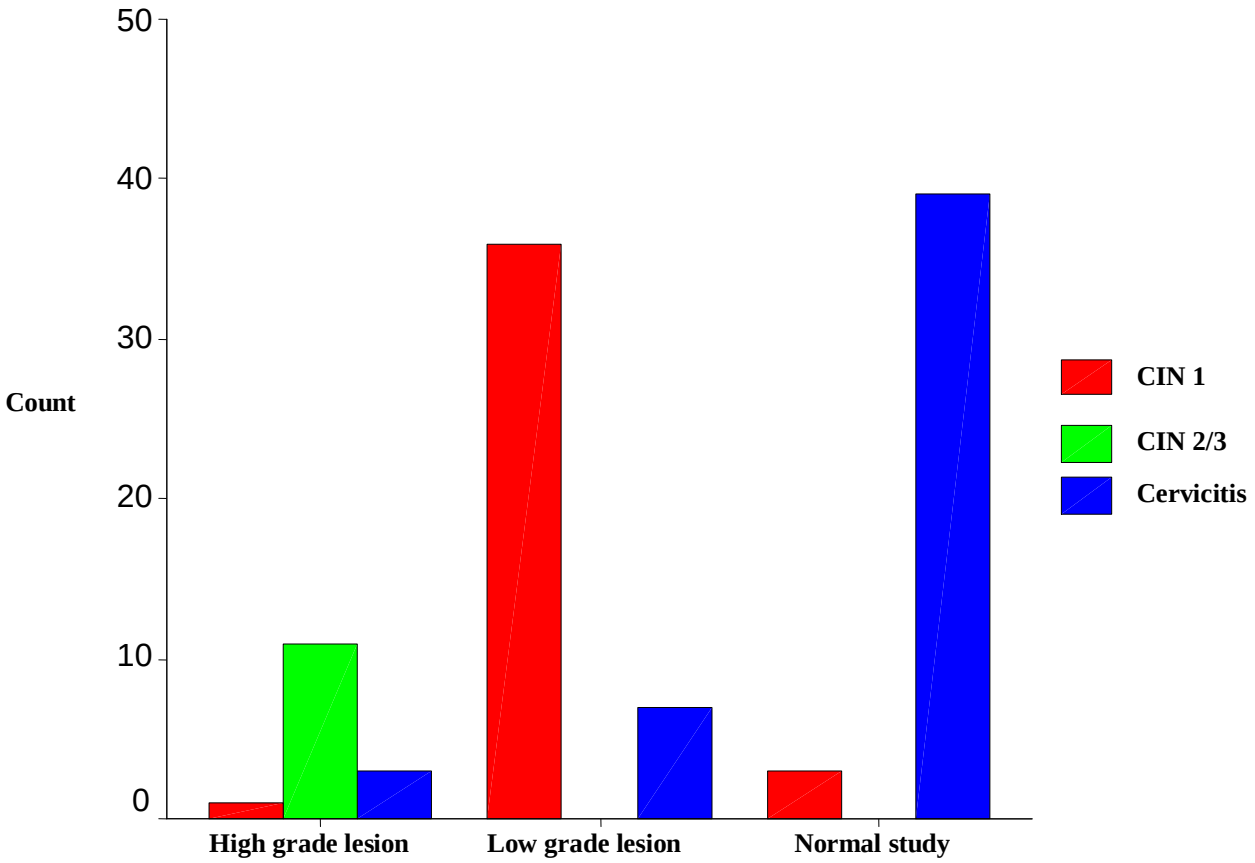
Among 100 women, 15% cases had high grade lesion, 43% case had low grade lesion and 42% had normal study.

Among high grade lesions group, one case that is 6.7% had CIN 1 , 73.3% had CIN2/3 and 3cases i.e., 20% had cervicitis.

Among low grade lesions group, 83.7% had CIN1 and 16.3% had cervicitis.

Among normal study group, 7.1% had CIN1 and 92.9% had cervicitis.

Table: 9
Colposcopy



SENSITIVITY AND SPECIFICITY OF COLPOSCOPY

Table: 10

Colposcopy		Biopsy		Total	Significant(P)
		CIN	Cervicitis		
Positive	Count	48	10	58	0.000
	% within Colposcopy	82.8%	17.2%	100.0%	
	% within Biopsy	94.1%	20.4%	58.0%	
Negative	Count	3	39	42	
	% within Colposcopy	7.1%	92.9%	100.0%	
	% within Biopsy	5.9%	79.6%	42.0%	
Total	Count	51	49	100	
	% within Colposcopy	51.0%	49.0%	100.0%	
	% within Biopsy	100.0%	100.0%	100.0%	

Correct estimation by Colposcopy = 87%

Under estimation by Colposcopy = 10%

Over estimation by Colposcopy = 3%

True Positive = 48

False Positive = 10

True Negative = 39

False Negative = 3

$$\text{Sensitivity} = \frac{\text{True Positive}}{\text{True positive + False Negative}} \times 100$$

$$= \frac{48}{48+3} \times 100 = 94.1\%$$

$$\text{Specificity} = \frac{\text{True Negative}}{\text{True Negative + False Positive}} \times 100$$

$$= \frac{39}{39+10} \times 100 = 79.6\%$$

$$\text{Positive Predictive Value} = \frac{\text{True Positive}}{\text{True Positive + False Positive}} \times 100$$

$$= \frac{48}{48+10} \times 100 = 82.8\%$$

$$\text{Negative Predictive Value} = \frac{\text{True Negative}}{\text{True Negative + False Negative}} \times 100$$

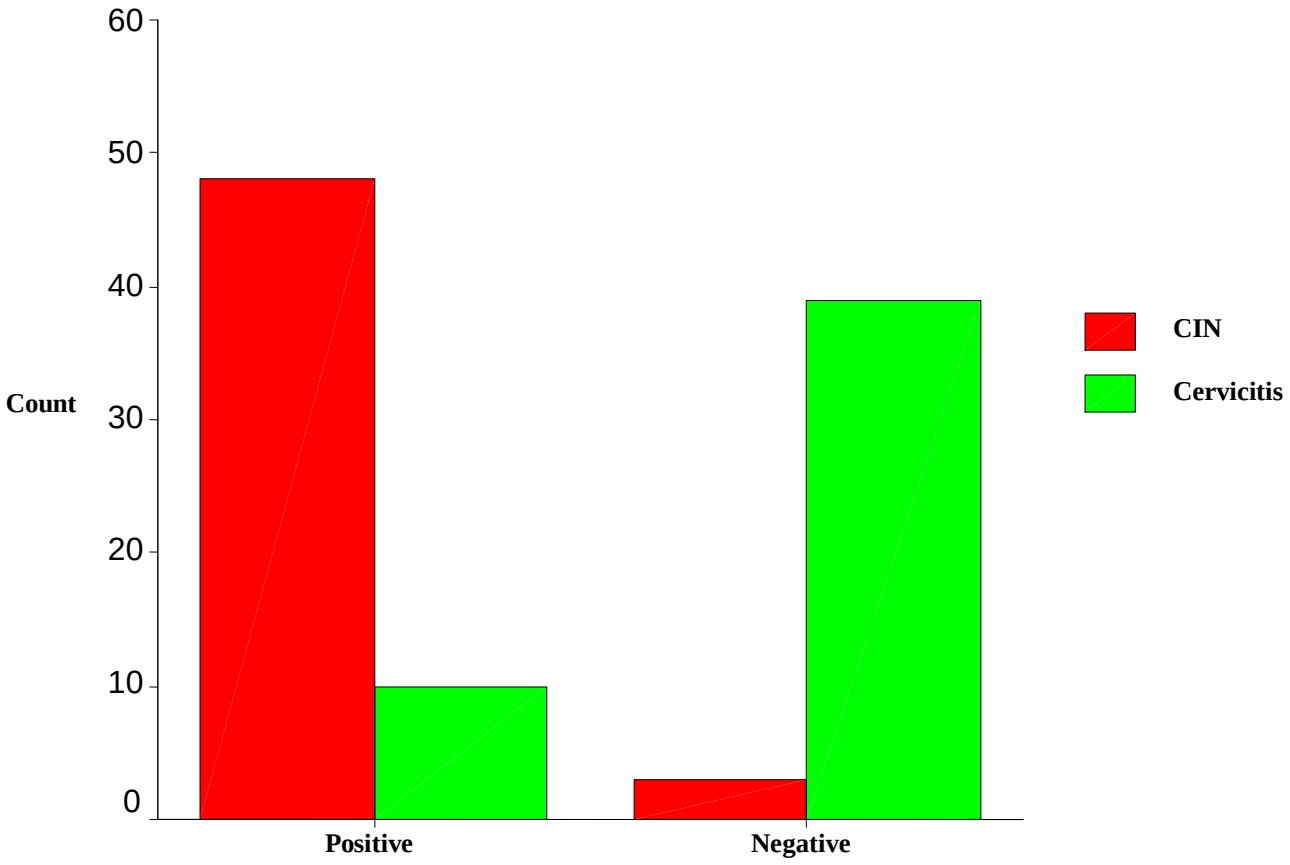
$$= \frac{39}{39+3} \times 100 = 92.9\%$$

$$\text{Accuracy} = \frac{\text{True Positive + True Negative}}{N} \times 100$$

$$= \frac{48+39}{100} \times 100 = 87\%$$

Table: 10

Sensitivity and Specificity of Colposcopy



PAP SMEAR
Table: 11

Pap smear		Biopsy			Total	Significant(P)
		CIN 1	CIN 2/3	Cervicitis		
ASCUS	Count	4	1	5	10	0.000
	% within PAP	40.0%	10.0%	50.0%	100.0%	
	% within Biopsy	10.0%	9.1%	10.2%	10.0%	
HSIL	Count	1	7	0	8	
	% within PAP	12.5%	87.5%	.0%	100.0%	
	% within Biopsy	2.5%	63.6%	.0%	8.0%	
LSIL	Count	31	2	1	34	
	% within PAP	91.2%	5.9%	2.9%	100.0%	
	% within Biopsy	77.5%	18.2%	2.0%	34.0%	
NIL	Count	1	0	43	44	
	% within PAP	2.3%	.0%	97.7%	100.0%	
	% within Biopsy	2.5%	.0%	87.8%	44.0%	
US	Count	3	1	0	4	
	% within PAP	75.0%	25.0%	.0%	100.0%	
	% within Biopsy	7.5%	9.1%	.0%	4.0%	
Total	Count	40	11	49	100	
	% within PAP	40.0%	11.0%	49.0%	100.0%	
	% within Biopsy	100.0%	100.0%	100.0%	100.0%	

Among 100 women ,10% had ASCUS, 8% had HSIL, 34% had LSIL, 44% had NIL and 4% had unsatisfactory reports.

Among ASCUS group, 40% had CIN1 lesion, 10% had CIN2/3 lesion and 50% had cervicitis.

Among HSIL group, 12.5% had CIN1 lesion and 87.5% had CIN2/3 lesion. None had cervicitis.

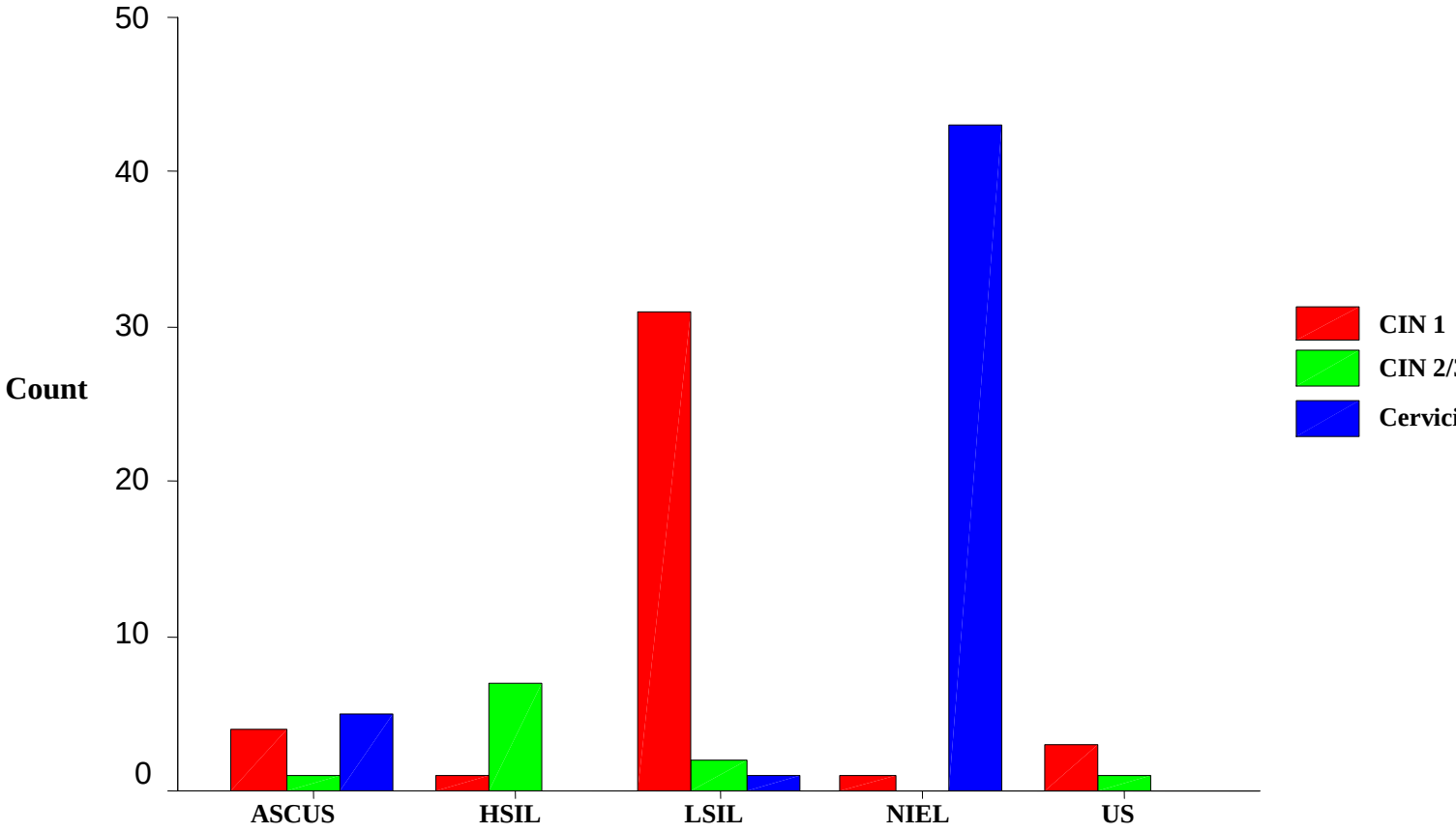
Among LSIL group , 91.2% had CIN1 lesion, 5.9% had CIN2/3 lesion and 2.9% had cervicitis.

Among NIL group , 2.3% had CIN1 lesion, none had CIN2/3 lesion and 97.7% had cervicitis.

Among US group , 75% had CIN1 lesion, 25% had CIN2/3 lesion. None had cervicitis.

Table: 11

PAP Smear



SENSITIVITY AND SPECIFICITY OF PAP SMEAR

Table: 12

Pap smear		Biopsy		Total	Significant(P)
		CIN	Cervicitis		
Positive	Count	46	6	52	0.000
	% within PAP	88.5%	11.5%	100.0%	
	% within Biopsy	90.2%	12.2%	52.%	
Negative	Count	5	43	48	
	% within PAP	10.4%	89.6%	100.0%	
	% within Biopsy	9.8%	87.8%	48%	
Total	Count	51	49	96	
	% within PAP	51%	49%	100.0%	
	% within Biopsy	100.0%	100.0%	100.0%	

Correct estimation by Pap smear = 89%

Under estimation by Pap smear = 6%

Over estimation by Pap smear = 5%

True Positive = 46

False Positive = 6

True Negative = 43

False Negative = 5

$$\text{Sensitivity} = \frac{\text{True Positive}}{\text{True positive + False Negative}} \times 100$$

$$= \frac{46}{46+5} \times 100 \qquad = 90.2\%$$

$$\text{Specificity} = \frac{\text{True Negative}}{\text{True Negative + False Positive}} \times 100$$

$$= \frac{43}{43+6} \times 100 \qquad = 87.8\%$$

$$\text{Positive Predictive Value} = \frac{\text{True Positive}}{\text{True Positive + False Positive}} \times 100$$

$$= \frac{46}{46+6} \times 100 \qquad = 88.5\%$$

$$\text{Negative Predictive Value} = \frac{\text{True Negative}}{\text{True Negative + False Negative}} \times 100$$

$$= \frac{43}{43+5} \times 100 \qquad = 89.6\%$$

$$\text{Accuracy} = \frac{\text{True Positive + True Negative}}{N} \times 100$$

$$= \frac{46+43}{100} \times 100 \qquad = 89\%$$

LIQUID BASED CYTOLOGY
Table: 13

Liquid Based Cytology			Biopsy			Total	Significant
			CIN I	CNN II/III	Cervicitis		
LBC	ASCUS	Count	1	0	0	1	0.000
		% within LBC	100.0%	0.0%	0.0%	100.0%	
		% within Biopsy	2.5%	0.0%	0.0%	1.0%	
	HSIL	Count	1	9	0	10	
		% within LBC	10%	90.0%	0.0%	100.0%	
		% within Biopsy	2.5%	81.8%	.0%	10.0%	
	LSIL	Count	36	2	1	39	
		% within LBC	92.3%	5.1%	2.6%	100.0%	
		% within Biopsy	90.0%	18.2%	2.0%	39.0%	
	NIL	Count	0	0	48	48	
		% within LBC	0.0%	0.0%	100.0%	100.0%	
		% within Biopsy	0.0%	0.0%	98.0%	48.0%	
	US	Count	2	0	0	2	
		% within LBC	100.0%	0.0%	0.0%	100.0%	
		% within Biopsy	5.0%	0.0%	0.0%	2.0%	
Total		Count	40	11	49	100	
		% within LBC	40.0%	11.0%	49.0%	100.0%	
		% within Biopsy	100.0%	100.0%	100.0%	100.0%	

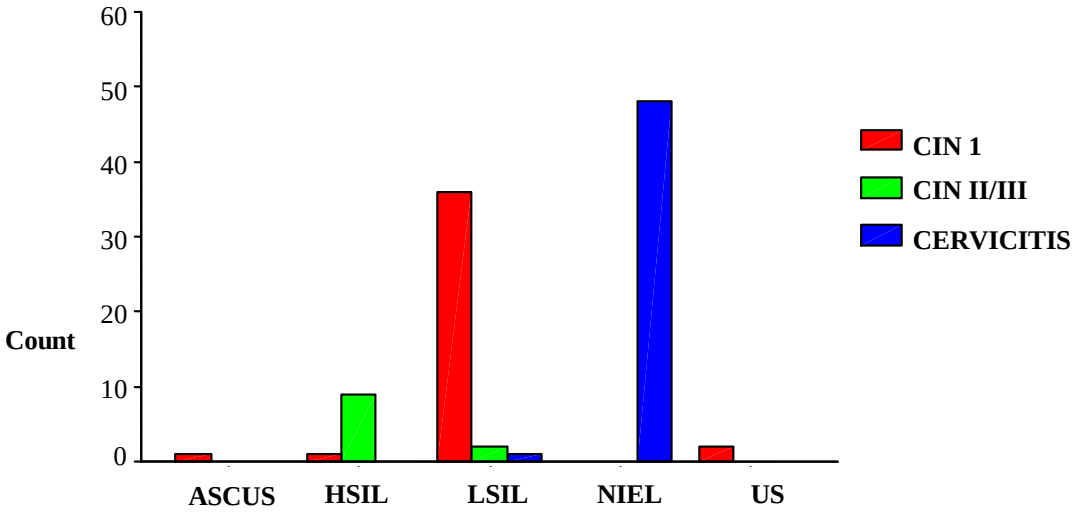
Among 100 women , 1% had ASCUS result , 10% belongs to HSIL group, 39% belongs to LSIL group and 2% had unsatisfactory result.

Among ASCUS group 100% had CIN I lesion. Among HSIL group , 10% had CIN I lesion and 90% had CIN II/III lesions.

Among LSIL group , 90% had CIN I lesions , 18.2% had CIN II/III lesions and 2% had cervicitis.

Among NIL group 90% had cervicitis. Among unsatisfactory group 100% had CIN I lesions.

Table: 13
Liquid Based Cytology



SENSITIVITY AND SPECIFICITY OF LIQUID BASED CYTOLOGY

Table: 14

Liquid Based Cytology			Biopsy		Total	Signifigant(P)
			CIN	Cervicitis		
LBC	Positive	Count	49	1	50	0.000
		% within LBC	98%	2%	100%	
		% within Biopsy	96.1%	2.0%	50%	
	Negative	Count	2	48	50	
		% within LBC	4%	96%	100%	
		% within Biopsy	3.9%	98%	50%	
Total		Count	51	49	100	
		% within LBC	51%	49%	100%	
		% within Biopsy	100%	100%	100%	

Correct estimation by Pap smear = 97%

Under estimation by Pap smear = 1%

Over estimation by Pap smear = 2%

True Positive = 49

False Positive = 1

True Negative = 48

False Negative = 2

$$\text{Sensitivity} = \frac{\text{True Positive}}{\text{True positive + False Negative}} \times 100$$

$$= \frac{49}{49+2} \times 100 = 96.1\%$$

$$\text{Specificity} = \frac{\text{True Negative}}{\text{True Negative + False Positive}} \times 100$$

$$= \frac{48}{48+1} \times 100 \qquad = 98\%$$

$$\text{Positive Predictive Value} = \frac{\text{True Positive}}{\text{True Positive + False Positive}} \times 100$$

$$= \frac{49}{49+1} \times 100 \qquad = 98\%$$

$$\text{Negative Predictive Value} = \frac{\text{True Negative}}{\text{True Negative + False Negative}} \times 100$$

$$= \frac{48}{48+2} \times 100 \qquad = 96\%$$

$$\text{Accuracy} = \frac{\text{True Positive + True Negative}}{N} \times 100$$

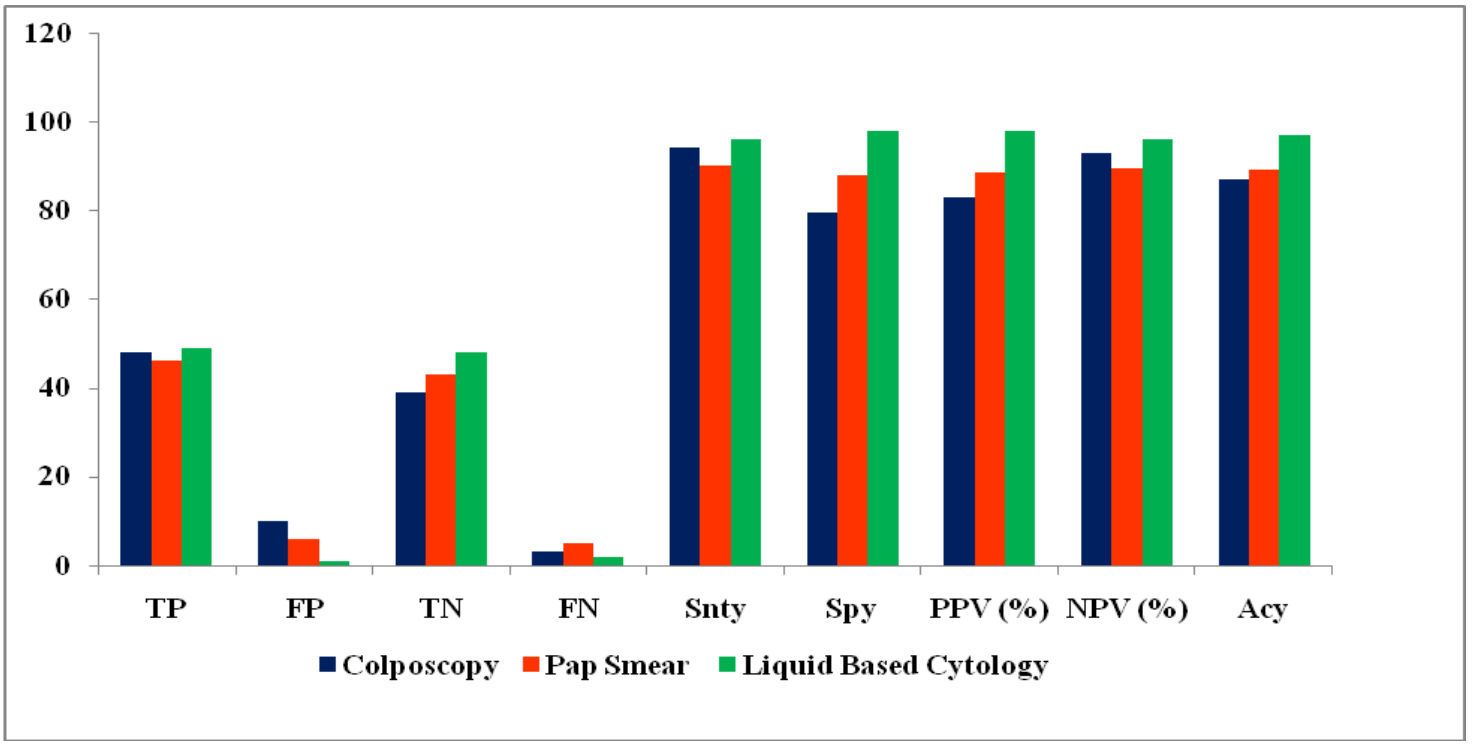
$$= \frac{49+48}{100} \times 100 \qquad = 97\%$$

ABSTRACT

Table: 15

Test	True Positive	False Positive	True Negative	False Negative	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Accuracy (%)
Colposcopy	48	10	39	3	94.1	79.6	82.8	92.9	87
Pap Smear	46	6	43	5	90.2	87.8	88.5	89.6	89
Liquid Based Cytology	49	1	48	2	96.1	98	98	96	97

Table: 15
Efficacy of Colposcopy, Pap Smear and LBC



DISCUSSION

Cervical cancer is the second most common cancer in developing countries. It is a preventable condition because it is associated with long precancerous duration making it amenable to screening and treatment. In this study, screening was done in 100 women in reproductive age groups with the complaints of lower abdominal pain, white discharge, menstrual irregularities. Most of the women have ectopy of the cervix and some have normal appearing cervix.

Regarding age distribution high incidence of CIN was found among 30 – 45 years of age group that is 86.2% of CIN lesions of all age groups. According to Kushtagi and Fernands study, the prevalence of CIN was higher in women over 30 years.(17) In Vaidhya's study CIN was more prevalent in the age group of more than 35 years.(34)

Duration of marriage and sexual exposure had a distinct role in genesis of CIN.

In this study, the incidence of CIN was 60.8% among women were married for more than 15 yaers. Kushtagi *et al.,* had demonstrated the severity of underlying CIN increased with the duration of marriage and sexual exposure.(17)

Increase incidence of CIN is found in multiparous women, in this study parity 3 and above have more incidence of CIN lesions i.e., 56.7% in para 3 group, 53.3% in para 4 or more group. Similar study was done by Shalini *et al.,* showed that the mean parity was 4.2 in patients with invasive cancer.(30) Kushtagi and Fernands showed that the prevalence was higher in parity of more than two(17) and Vaidhya 's study also showed more cases of CIN were

found with parity more than 4.(34) This is due to hormonal and nutritional changes occur in pregnancy also due to immunosuppression in pregnancy and cervical trauma during vaginal delivery (Becker *et al.,* and Adadevon *et al*.,(2)

Socio-economic status plays an important role in the development of CIN lesions. In this study, increased incidence of CIN was found in class 5 socio-economic status group. i.e., 64,7%. Vaidhya's study also showed definitive role of socio-economic status in the development of dysplasia, i.e., 80% of CIN I and 50% of CIN II were from lower income group.(34) Poor hygiene, poor standard of living, multiple sexual partners and early exposure to sexual life are the factors associated with both lower income groups and cervical dysplasias.

In this study, 60.8% of women with leucorrhoea had CIN lesions. Leucorrhoea plays an important role in the development of CIN. Vaidhya *et al*., also proved the above relation with leucorrhoea by 24% of vaginal discharge.(34)

Regarding the cervical appearances by clinical examination, the most common finding is cervical ectopy, where the columnar epithelium replaces the squamous epithelium. Ectopy was seen 61% women, among them 52.5% had lesions.

Among 100 women who underwent **Colposcopy**, 15% cases had high grade lesions, 43% cases had low grade lesions and 42% had normal study. In high grade lesion group, only 73.3% had CIN 2/3 findings. In low grade lesion group , only 83.7% had CIN 1 lesion. In normal study group , 92.9% had cervicitis.

In this study correct estimation of Colposcopy was 87%, the sensitivity was 94.1% and the specificity was 79.6%. The positive predictive value of this test was 82.8% and the negative predictive value of this test was 92.9%.

Sensitivity and Specificity of Colposcopy by various authors

Author	Sensitivity (%)	Specificity (%)
Pimple SA *et al.*,	58 – 74.7	57.5 – 92.9
Olaniyan B (Meta analysis)	87 – 99	26 – 87
Divya Hegde *et al.*,	70.8	95
Shuchiconsul *et al.*,	94.7	48.3
Sukhpreet L: Singh *et al.*,	95	63.5
Present Study	94.1	79.6

Divya Hegde *et al.*, study showed that the sensitivity was 70.8%, the specificity was 95%, PPV was 62.9%, NPV was 96.5%.(7)

The meta analysis study by Olaniyan B *et al.*, showed that there was high correlation between the Colposcopy and biopsy, the accuracy was 89%. The present study also had the accuracy rate of 87%.(23)

The Colposcopy is the best screening tool because it had low false negative rate i.e., 3% and high accuracy rate of 87% which is well correlated with biopsy reports.

In **Pap smear** study, among 10 women , 10% had ASCUS, 8% had HSIL, 34% had LSIL, 44% had NIL and 4% had unsatisfactory reports.

In ASCUS group , 40% had CIN 1 lesion, 10% had CIN 2 lesions and 50% had cervicitis . In HSIL group, 87.5% had CIN 2/3 lesions. In LSIL group, 91.2% had CIN 1 lesion. In NIL group , 97.7% had cervicitis.

In the present study , Pap smear had sensitivity rate of 90.2%. The specificity was 87.8% and test of accuracy was 89%.

Author	Sensitivity (%)	Specificity (%)
Donald Angstetra *et al.,*	87 -88.6	56.4 – 84.7
Pimple SA *et al.,*	57.4	99.4
Sherwani RK *et al.,*	53.7	50
Matto Sinho de Castro Ferraz Mda G *et al.,*	81.8	85.2
Hussain T *et al.,*	83	82
Longatto Filho A *et al*	59	97
Divya Hegde *et al.,*	83	98
Present study	90.2	87.8

The specificity and sensitivity of the present study was correlated with Divya Hegde *et al.,* study.(7)

The Pap smear had high sensitivity, specificity and accuracy rate. The reports are well correlated with biopsy reports. So the Pap smear also the best screening tool.

In **LBC** study, among 100 women , 1% had ASCUS, 10% had HSIL, 39% had LSIL, 48% had NIL and 2% had unsatisfactory reports.

In ASCUS group , that one case showed CIN 1 result. In HSIL group , 90% had CIN 2/3 lesions. In LSIL group , 92.3% had CIN 1 lesion. In NIL group all cases had cervicitis.

The present study revealed good correlation between LBC and Biopsy reports. It had high sensitivity rate of 96.1% and specificity of 98%. The PPV was 98%, NPV was 96% and accuracy rate was 97%.

Author	**Sensitivity (%)**	**Specificity (%)**
Donald Angstetra *et al.,*	86.6 – 89.1	53.8 – 83.1
Sherwani RK *et al.,*	97.6	50
Matto Sinho de Castro Ferraz Mda G *et al.,*	75.3	86.4
Hussain T *et al.,*	92	76
B.M. Van Hemel *et al*	68.3 – 89.4	91.4 – 92.8
Present Study	96.1	98

Sherwani RK *et al.,* and Hussein T *et al.,* reported that the sensitivity was 97.6% and 92% respectively and this result was correlated with the present study results.(31)

The specificity by B.M. VanHemel's study showed 92.8% and this result was in accordance with the present study.(35)

In this study, LBC is having higher sensitivity and specificity and accuracy rate than colposcopy and Pap smear. The sensitivity and specificity of combined Colposcopy and pap smear is almost equal to LBC results. Since LBC is more expensive, in our settings we can use the combined Colposcopy and Pap smear for the cervical cancer screening.

SUMMARY

The present study was a prospective study conducted at ISO and KGH, Chennai in the Department of Obstetrics and Gynecology during the period January 2011 to November 2012. The study was conducted in 100 women who fulfilled the selection criteria and they were randomly selected from Gynecology OP. after getting informed consent from all women Colposcopy, Pap smear, Liquid based cytology and Cervical biopsy were done. All the results were tabulated and analyzed.

To summarize,

1. Majority of CIN lesions occurred i.e., 83% in the age group of 30-45 years.

2. High incidence of CIN lesions seen in early marriage i.e., 74% in less than 19 years (age at marriage).

3. High incidence of CIN lesions occurred in long duration of sexual exposure i.e., 60.8% (more than 15 years duration).

4. Majority of CIN lesions occurred in class 5 Socio-economic status i.e., 41%.

5. The incidence of CIN was high among high parity people i.e., more than 50% in Para 3 and above group.

6. Among 100 women , high incidence of CIN lesions i.e., 47% found in LCB more than 11 years group.

7. In symptoms wise high incidence of CIN i.e., 60.8% present in leucorrhoea group.

8. Among 100 women , 61% had ectopic findings on examination.

9. Colposcopy had high sensitivity of 94.1% and specificity of 79.6%. The PPV was 82.8%, NPV was 92.9% and the accuracy rate of 87%.

10. In this study based on the results, Colposcopy can be used as the best screening tool.

11. Pap smear showed high sensitivity of 90.2%, specificity of 87.8%, PPV of 88.5% , NPV of 89.6% and accuracy rate of 89%. So this is also an effective screening method.

The study concluded that LBC had more sensitivity and specificity than Colposcopy and Pap smear i.e., the sensitivity was 96.1%, the specificity was 98%, the PPV was 98%, the NPV was 96% and the Accuracy was 97%. Of all the three LBC showed the best results.

In this study, LBC is having higher sensitivity and specificity and accuracy rate than colposcopy and Pap smear. The sensitivity and specificity of combined Colposcopy and pap smear is almost equal to LBC results. Since LBC is more expensive, in our settings we can use the combined Colposcopy and Pap smear for the cervical cancer screening.

CONCLUSION

Early diagnosis and treatment is the best tool for the prevention cancer cervix. Cancer cervix has long precancerous course and it makes amenable to screening and treatment.

This study concluded that accuracy, sensitivity and specificity of LBC was higher than the Pap smear and Colposcopy, but it is more expensive. It is not used routinely a screening procedure in low resource settings i.e., in developing and under developed countries.

Colposcopy had higher sensitivity and requires single visit for screening and treatment. Pap smears require frequent visits for getting reports and further treatment. Colposcopy is used for both screening and treatment.

In this study Pap smear had more specificity rate when compared with Colposcopy. But it had more unsatisfactory rates and need further tests and results compared with Colposcopy.

Colposcopy and Pap smear both are available in all government settings and frequently used as the screening procedures. VIA and VILI are used in all health camps.

All health care providers are trained well in VIA and VILI. They screened in all women and referred the positive cases to higher institutions. Both Colposcopy and Pap smear combined results showed best sensitivity and specificity. They are complementary to one another, so both of them can be used as the best screening tools.

BIBLIOGRAPHY

1.Atlas of Colposcoy, Per kolstad M.D, IIIrd Edition 1977, Churchill living stone.

2.Adadevoh S.W; Forkoh B.K; Cervical cancer Screening. International Journal of Gynaecology and Obstetrics; Oct 1993; 43(1): 63-4

3.Basu P.S, Sankaranarayanan. R, Mandal. R, Roy. C, Das. P, Visual Inspection of Cervix with acetic add and cytology in the early detection of cervical neoplasia in Kolkotta - India. International Journal of Cancer 2005; Sept - Oct 13 (6) 626 - 632.
BHJ, No.4, Vol 42, Oct 2000.

4.Benedict.J.L, Matistic.J P,Bertrand M.A, An analysis of 84244 patients from the
British Columbia Cytology-colposcopy program.J.Gynecol 2004; Jan 92(1): 127-134

5.Camille Andy,Linda F Turner. Is the thin prep better than conventional papsmear at detecting cervical cancer. The Journal of Family Practice 2002; 53: 4

6.Christian Garbar, Corinne Mascaux, Veronique Fontaine. Efficiency of an inexpensive liquid-based cytology performed by cytocentrifugations: a comparative study using the histology as reference standard. CytoJournal 2005, 2:15.

7.Divya Hegde, Harish Shetty, Prasanna K. Shetty, Supriya Rai. Diagnostic value of acetic acid comparing with conventional Pap smear in the detection of colposcopic biopsy-proved CIN. Journal of Cancer Research and Therapeutics. 2011; 7(4): 454-458.

8.Donald Angstetra, Thomas Tait, Jaffery Tan and Ian Symonds. Should liquid based cytology be performed prior to colposcopy? A comparison of the accuracy, unsatisfactory rates and cost in a referral setting. Australian and New Zealand J Obstetrics and Gynaecology. 2009; 49: 681-684.

9.Duggan et al, Natural History of CIN & Lesions, European J. Gynaecol. Oncol 1988, 19 (4) 338 - 44.

10.Elizabeth davey, Jefferson d'Assuncao, Lea Irwig, Petra Macaskill, Siew F Chan, Adele Richards, Annabelle Farnsworth. Accuracy of reading liquid based cytology slides using the thinprep imager compared with conventional cytology: prospective study. BMJ 2007, 335: 31-5.

11.Etherington. JJ, Telecolposcopy - A feasibility study in primary care, Dept. of Obs. & Gyn, City Hospital, Birmingham, J. Telemed Telecare 2002; 8 supp 2 : 22 - 4.

12.Fine B A, Fienstein G.E, Sabella.V, The Pre and postoperative value of endocervical curettage in the detection of CIN and invasive cancer, Gynaecol oncol, Oct 1998. 71(1) 46-9

13.Hao Deshou, Wang Changhua, Li Qinyan, Liu Wei, and Fu Wen. Clinical utility of Liqui-PREP™ cytology system for primary cervical cancer screening in a large urban hospital setting in China. J Cytol. 2009; 26(1): 20–25.

14.Hussein T, Desai M, Tomlinson A, Kitchener HC. The comparative diagnostic accuracy of conventional and liquid-based cytology in a colposcopic setting. BJOG. 2005; 112(11): 1542-6.

15.Jie Zhu, Ingrid Norman, Kristina Elfgren, Vera Gabri, Bjorn Hagmar, Anders Hjerpe and Sonia Anderson. A comparison of liquid-based cytology and Pap smear as a screening method for cervical cancer. Oncology Reports. 2007; 18: 157-160.

16.Jin h, Wang Y, Lin, Cheng X, Zeng H, Systematic Evaluation of the New Screening Methods of CIN, Chinese Journal, 2002, March, 37 (3) : 157-60.

17.Kushtagi P, Fernandez. P, Significance of Persistent Inflammatory, Cervical smears in Sexually active women of reproductive age. The Journal of Obs and Gyn. of India, 2002, Jan - Feb ; 52 (1) : 124 - 6.

18.Longatto-Filho A, Maeda MY, Erzan M, Branca M, Roteli-Martins C, Naud P, Derchain SF, Hammes L, Matos J, Goniko R, Sairan LO, Lima TP, Tatti S, Syrjanen S, Syrjanen K. Conventional Pap smear and liquid based cytology as screening tools in low-resource settings in Latin America: experience of the latin American screening study. Acta Cytol. 2005; 49 (5): 500-6.

19.Malcolm Coppleson Gynaecol oncology , volume 2 Edition 1992, Churchill Livingstone Publication.

20.Mattosinho de Castro Ferraz Mda G, Nicolau SM, Stavale JN, Focchi J, Castelo A, Dores GB, Mielzynska-Lohnas I, Lorincz A, Rodrigues de Lima G. Cervical biopsy-based comparison of a new liquid-based thin layer preparation with conventional Pap smears. Diagn Cytopathol. 2004; 30(4): 220-6.

21.Michael S . Baggish, Colposcopy of the cervix, vagina and vulva- A Comprehensive Text Book, 2003 , Mos by.

22.Novak's Gynaecology, 13 Edition ; Intraepithelial disease of early cervical neoplasia, vagina and vulva, 2002; P: 47-50

23.Olaniyan O.B. Validity of Colposcopy in the diagnosis of early cervical neoplasia a review - African Journal of Reproductive Health 2002, 6: 59-69

24.Park IA, Lee SN et al. Comparing the accuracy of thin prep pap tests and conventional pap smears on the basis of histologic diagnosis – A Clinical Study. Acta Cyto 2001; 45: 525 – 31.

25.Pimple SA, Amin G, Goswani S, Shastri SS. Evaluation of colposcopy vs cytology as secondary test to triage women found positive on visual inspection test. Indian Journal of cancer. 2010; 47(3): 308-312.

26.Randall K Gibb, and Mark G Martens. The Impact of Liquid-Based Cytology in Decreasing the Incidence of Cervical Cancer. Rev Obstet Gynecol. 2011; 4(Suppl 1): S2–S11.

27.Reinhard Bollmann,Wolfgang Kuhn,Berlin, Liquid based cytology…Gynakol Geburts med Gynakol Endokrinol 2008;4(2): 164-180.

28.RK Sherwani, T Khan, K Akhtar, A Zeba, FA Siddiqui, K Rahman, N Afsan. Conventional Pap smear and liquid based cytology for cervical cancer screening - a comparative study. J cytol. 2007; 24 (4): 167-172.

29.Sankaranarayanan R, J.W. Sellers, Colposcopy and Treatment of CIN, A Beginner's Manual. IARC Working Group.

30.Shalini. R, Amita. S, Neera. M.A, How alarming is post coital bleeding – a cytologic, colposcopic and histological evaluation Gynaecol Obstet Invest. 1998, 45(3) : 205 - 8.

31.Sherwani RK, Khan T et al., Conventional Pap smear and liquid based cytology for cervical cancer screening – A comparative study. Journal of cytology. 2011; 24(4): 167 – 172.

32.Shuchi Consul, Awinash Agarwal,Hemel Sharma,Anita Bansal, Manish Gutch, Nirdesh Jain Comparative Study of effectiveness of papsmear versus visual inspection with acetic acid and visual inspection with lugol's iodine for mass screening of premalignant and malignant lesion of cervix. Indian Journal Medical Paediatric Oncology,Nov 2012;33: 161-165.

33.Sukhpreet L Singh, Nayana A Dastur, Murari S. Nanavatti; Comparison of colposcopy and pap smear : Sensitivity, specificity and predictive values

34.Vaidya A, Comparison of pap test among high risk and non risk female, kathmandu university, medical journal, 2003, Vol 1, No. 1, P: 8-13.

35.Van Hemel BM, Buikema HJ, Groen H, Suurmeijer AJ. Accuracy of a low priced liquid-based method for cervical cytology in 632 women referred for colposcopy after a positive Pap smear. Diagn Cytopathol. 2009; 37(8): 579-83.

36.Williams AR, Liquid Based cytology and conventional Smears compound over two 12 – month periods. Cytopathology Apr 2006; 17(12): 82 – 5

37.Yarandi F, Izadi Mood N, F, Eftekhar Z, Colposcopic and histrologic findings in a women with cytologic diagnosis of atypical squamous cells of undetermined significance. Aust NZ Johshet. Gynaecol, Dec 2004:44(6): 514-6

38.Zhu J, Norman I, Elfgren K, Gaberi V, Hagmar B, Hjerpe A, Andersson S. A comparison of liquid-based cytology and Pap smear as a screening method for cervical cancer. Oncol Rep. 2007 Jul; 18(1):157-60.

PROFORMA

Serial Number : Name :
OP Number : Age :
Income :

I. COMPLAINTS

1. White discharge PV
   - Duration
   -Quantity
   -Colour
   -Pruritus
   - foul smell

2. Menstrual disturbances
   -Regular or Irregular
   -Duration and amount
   - Associated Pain
   - Post coital bleeding
   - Inter menstrual bleeding
3. Lower abdomen
4. Urinary symptoms
5. Bowel Symptoms
6. Others

II PERSONAL HISTORY
Diet
Hygiene

III MENSTRUAL HISTORY
Age at menarche
Cycles
LMP

IV. MARTIAL HISTORY
.Age
.Duration

V. OBSTETRIC HISTORY
.PLA
.LCB

VI. GENERAL EXAMINATION

Built thyroid
Anemia Breast
Pedal edema BP
Lymphadenopathy PR
CVS RS

VII. PER ABDOMEN

VIII. LOCAL EXAMINATION OF GENITALIA

IX. SPECULUM EXAMINATION

.Cervix
.Vagina

X. PAPSMEAR

XI. COLPOSCOPIC EXAMINATION

.Normal saline
.Green filter
. Acetic Acid
.Lugol's Iodine

XII. COLPOSCOPIC FINDINGS

Normal TZ.
Abnormal Acetowhite.
Iodine Negative.
Others
Ectopy
Metaplasia.

XIII. PER VAGINAL EXAMINATION.

Xiv. PER RECTAL EXAMINATION

XV. BIOPSY.

MASTER CHART

Name	Age	OPNO	Age-Men	Dur-mar	Age-mar	SES	Parity	LCB	Symptoms	S/E	Colposcopy	PAP	LBC	Biopsy
Dhilsathbegam	42	28301	14	25	17	5	P3L3	14	Leucorrhoea	Ectopy	Low grade lesion	LSIL	LSIL	CIN-1
Mallika	40	30481	17	21	19	5	P4L4	15	Leucorrhoea	Ectopy	High grade lesion	LSIL	LSIL	CIN-2
Vani	34	30479	13	17	17	4	P4L4	6	Leucorrhoea	Ectopy	High grade lesion	HSIL	HSIL	CIN-2
Annipesant	28	30295	15	8	20	4	P3L3	4	Leucorrhoea	Ectopy	High grade lesion	HSIL	HSIL	CIN-2
Selvi	36	10379	11	13	23	3	P2L2	10	Leucorrhoea	Ectopy	Normal study	NIL	NIL	Cervicitis
Poongodi	36	25853	11	19	17	5	P2L2	15	Low AbdPain	Ectopy	Low grade lesion	LSIL	LSIL	CIN-1
Valli	35	30475	14	18	17	4	P4L2	13	Screening	Ectopy	Low grade lesion	NIL	NIL	Cervicitis
Jabeenabegam	27	29355	14	6	21	5	P2L2	1	Low AbdPain	Normal	Normal study	NIL	NIL	Cervicitis
Usharani	42	19098	12	22	20	5	P4L4	17	Low AbdPain	Normal	High grade lesion	HSIL	HSIL	CIN-2
Renuga	40	29903	14	23	17	3	P4L3	17	Low AbdPain	Ectopy	High grade lesion	NIL	NIL	Cervicitis
Amudha	35	3586	15	19	16	5	P2L2	14	Low AbdPain	Ectopy	High grade lesion	HSIL	HSIL	CIN-2
Saritha	30	10313	13	13	17	4	P3L2	10	Leucorrhoea	Normal	Normal study	NIL	LSIL	CIN-1
Rajam	42	1360	12	26	16	5	P2L2A1	20	Low AbdPain	Ectopy	High grade lesion	HSIL	HSIL	CIN-1
Sulochana	42	315	15	24	18	3	P3L2	20	Low AbdPain	Ectopy	Normal study	NIL	NIL	Cervicitis
Sasikala	30	3594	12	7	23	4	P2L2	3	Men Dis	Normal	Low grade lesion	LSIL	LSIL	CIN-1
Vasuki	33	16127	13	16	17	5	P2L2	11	Low AbdPain	Normal	Low grade lesion	LSIL	LSIL	CIN-1
Chitra	37	32872	14	20	17	5	P2L2	17	Leucorrhoea	Ectopy	High grade lesion	HSIL	HSIL	CIN-2
Roja	42	5947	15	23	19	4	P4L4	12	Leucorrhoea	Normal	High grade lesion	HSIL	HSIL	CIN-2
Devi	26	36873	14	6	20	3	P2L2	4	Leucorrhoea	Ectopy	Metaplasia	ASCUS	NIEL	Cervicitis
Devi	28	8301	13	12	16	4	P2L2	10	Leucorrhoea	Ectopy	High grade lesion	NIL	NIL	Cervicitis
Saraswathi	42	6514	12	24	18	4	P2L2	20	Low AbdPain	Normal	High grade lesion	LSIL	HSIL	CIN-2
Malarvizhi	34	1787	13	13	21	4	P2L1	9	Leucorrhoea	Normal	Low grade lesion	NIL	NIL	Cervicitis
Rani	43	7662	13	26	17	3	P3L0	20	Leucorrhoea	Normal	Low grade lesion	ASCUS	NIL	Cervicitis
Nageshwari	30	7437	13	12	18	5	P2L2	10	Leucorrhoea	Normal	Low grade lesion	LSIL	LSIL	CIN-1
Gnanasoundari	39	4971	14	23	16	5	P5L5	13	Men Dis	Normal	High grade lesion	ASCUS	LSIL	CIN-2
Loganayaki	40	5954	13	24	16	3	P7L3	13	Leucorrhoea	Normal	Metaplasia	NIL	NIL	Cervicitis
Kalaivani	32	5173	13	13	19	4	P3L3	10	Leucorrhoea	Ectopy	Low grade lesion	LSIL	LSIL	CIN-1
Gowri	35	8255	13	19	16	3	P2L2	12	Leucorrhoea	Ectopy	Metaplasia	NIL	NIL	Cervicitis
Kumari	37	19454	14	21	18	5	P3L2	12	Low AbdPain	Normal	Low grade lesion	LSIL	LSIL	CIN-1
Devi	28	3772	13	11	17	3	P3L3	8	Leucorrhoea	Normal	Normal study	NIL	NIL	Cervicitis
Dhanalakshmi	38	6936	14	21	17	3	P4L4	10	Low AbdPain	Ectopy	Metaplasia	NIL	NIL	Cervicitis
Anjalai	28	10443	13	11	17	5	P4L4	6	Leucorrhoea	Ectopy	Normal study	LSIL	LSIL	CIN-1
Jayanthi	30	8875	12	15	15	5	P2L2	5	Low AbdPain	Ectopy	Low grade lesion	US	LSIL	CIN-1
Nagajothi	26	6761	13	8	18	3	P2L2	3	Leucorrhoea	Ectopy	High grade lesion	NIL	NIL	Cervicitis

Zamuruth	30	7682	13	13	17	4	P3L3	8	Leucorrhoea	Ectopy	Low grade lesion	NIL	NIL	Cervicitis
Thenmozhi	36	11322	12	20	16	5	P2L2	13	Leucorrhoea	Normal	Low grade lesion	LSIL	LSIL	CIN-1
Valarmathi	30	11343	12	11	19	4	P2L2	8	Leucorrhoea	Ectopy	Low grade lesion	LSIL	LSIL	CIN-1
Mallika	37	11013	13	20	17	4	P2L2	15	Leucorrhoea	Ectopy	Normal study	NIL	NIL	Cervicitis
Sudha	30	10340	12	6	24	5	P2L2A1	6	Leucorrhoea	Normal	Normal study	NIL	NIL	Cervicitis
Leelavathi	40	4744	13	20	20	3	P1L1	19	Low AbdPain	Normal	Normal study	NIL	NIL	Cervicitis
Andal	38	10199	12	15	23	3	P3L3	5	Leucorrhoea	Normal	Low grade lesion	NIL	NIL	Cervicitis
Lakshmi	32	6653	13	15	17	5	P3L3	3	Leucorrhoea	Ectopy	Low grade lesion	LSIL	LSIL	CIN-1
Banumathi	30	11010	13	12	18	5	P2L2	2	Leucorrhoea	Ectopy	Normal study	LSIL	LSIL	CIN-1
Valli	36	9945	14	15	21	3	P2L2	12	Leucorrhoea	Normal	Normal study	NIL	NIL	Cervicitis
Dhanalakshmi	30	8915	13	13	17	5	P4L4	5	Leucorrhoea	Ectopy	Low grade lesion	LSIL	LSIL	Cervicitis
Maheswari	28	7371	12	12	16	4	P3L3A1	4	Low AbdPain	Normal	Low grade lesion	US	ASC US	CIN-1
Jothilakshmi	27	11277	13	10	17	5	P2L2	8	Leucorrhoea	Normal	Low grade lesion	LSIL	LSIL	CIN-1
Noornisha	38	10336	12	23	15	5	P4L4	13	Men Dis	Normal	Low grade lesion	LSIL	LSIL	CIN-1
Loganayaki	42	10304	13	25	17	4	P4L4	12	Leucorrhoea	Normal	High grade lesion	HSIL	HSIL	CIN-3
Baragath	41	11023	13	21	20	3	P4L4	12	Leucorrhoea	Ectopy	Normal study	NIL	NIL	Cervicitis
Kiruba	37	13181	12	20	17	5	P2L2A1	14	Low AbdPain	Ectopy	Low grade lesion	LSIL	LSIL	CIN-1
Revathi	29	11038	14	12	17	5	P2L2	6	Leucorrhoea	Ectopy	Low grade lesion	ASC US	LSIL	CIN-1
Guna	36	13485	12	18	18	5	P3L3	12	Men Dis	Ectopy	Low grade lesion	LSIL	LSIL	CIN-1
Baby	33	12912	13	14	19	3	P2L2A2	10	Screening	Ectopy	Normal study	NIL	NIL	Cervicitis
Suseela	36	12791	14	16	20	4	P2L2	12	Screening	Ectopy	Low grade lesion	LSIL	LSIL	CIN-1
Deepa	27	11005	13	7	20	5	P2L2	3	Leucorrhoea	Ectopy	Low grade lesion	LSIL	LSIL	CIN-1
Suguna	42	13616	12	20	22	3	P3L3	15	Low AbdPain	Ectopy	Normal study	NIL	NIL	Cervicitis
Kalavathi	40	14122	13	20	20	3	P4L4	13	Low AbdPain	Ectopy	Normal study	NIL	NIL	Cervicitis
Valli	37	17510	14	19	18	3	P2L2	10	Leucorrhoea	Ectopy	Normal study	NIL	NIL	Cervicitis
Meenatchi	28	28175	12	10	18	3	P2L2A1	2	Leucorrhoea	Ectopy	Normal study	NIL	NIL	Cervicitis
Nadhiya	28	13832	13	10	18	3	P2L2A1	3	Leucorrhoea	Normal	Metaplasia	NIL	NIL	Cervicitis
Mahalakshmi	33	33627	12	16	17	3	P2L2A1	10	Leucorrhoea	Normal	Normal study	NIL	NIL	Cervicitis
Umamaheswari	37	24761	13	21	16	3	P3L3	13	Leucorrhoea	Normal	Normal study	NIL	NIL	Cervicitis
Jayakodi	30	30844	12	12	18	5	P3L3	5	Leucorrhoea	Ectopy	Low grade lesion	ASC US	LSIL	CIN-1
Amudha	35	5433	13	12	23	4	P2L2	7	Leucorrhoea	Ectopy	High grade lesion	US	HSIL	CIN-2
Subbulakshmi	33	15297	12	10	23	4	P2L2A1	7	Leucorrhoea	Ectopy	Normal study	NIL	NIL	Cervicitis
Samsathbegum	40	108	14	20	20	5	P3L3	12	Low AbdPain	Ectopy	Normal study	NIL	NIL	Cervicitis
Latha	40	14247	13	19	21	5	P2L2	16	Low AbdPain	Normal	Normal study	NIL	NIL	Cervicitis
Mariammal	30	188	14	13	17	3	P2L2	9	Leucorrhoea	Normal	Metaplasia	NIL	NIL	Cervicitis
Gowri	32	15812	11	12	20	5	P2L2A1	8	Men Dis	Normal	Normal study	NIL	NIL	Cervicitis
Punitha	24	13210	13	7	17	5	P2L2A1	3	Men Dis	Ectopy	Low grade lesion	ASC US	LSIL	CIN-1

Kamali	42	10343	15	25	17	4	P2L2A1	15	Leucorrhoea	Ectopy	Low grade lesion	LSIL	LSIL	CIN-1
Glory	40	1339	12	20	20	5	P2L2	15	Leucorrhoea	Normal	Low grade lesion	LSIL	US	CIN-1
Lakshmi	35	13360	11	16	19	4	P2L2	13	Leucorrhoea	Normal	Normal study	ASC US	NIL	Cervicitis
Sairabanu	33	37260	13	17	16	5	P3L3	11	Leucorrhoea	Ectopy	Low grade lesion	LSIL	LSIL	CIN-1
Jayalakshmi	34	30658	12	16	18	5	P3L3	6	Low AbdPain	Normal	Low grade lesion	LSIL	LSIL	CIN-1
Kamatchi	38	14710	11	21	17	3	P3L3	6	Leucorrhoea	Ectopy	Metaplasia	NIL	NIL	Cervicitis
Ponni	32	11238	12	15	17	3	P3L3	9	Leucorrhoea	Normal	Low grade lesion	LSIL	LSIL	CIN-1
Geetha	34	16069	13	18	16	5	P2L2A1	9	Leucorrhoea	Ectopy	Low grade lesion	US	US	CIN-1
Parimala	27	7865	12	5	22	5	P2L2	3	Screening	Ectopy	Normal study	NIL	NIL	Cervicitis
Allimalar	29	9764	14	10	19	3	P2L2	7	Low AbdPain	Ectopy	Normal study	NIL	NIL	Cervicitis
Gunasundari	41	15088	12	16	25	4	P2L2A1	10	Leucorrhoea	Ectopy	Low grade lesion	ASC US	LSIL	CIN-1
Padma	38	13342	11	17	21	3	P3L3	8	Low AbdPain	Normal	Normal study	NIL	NIL	Cervicitis
Geetha	32	37150	13	13	19	5	P2L2A1	5	Leucorrhoea	Ectopy	Metaplasia	NIL	NIL	Cervicitis
Kalaivani	30	16211	12	14	16	5	P3L3	6	Leucorrhoea	Ectopy	Low grade lesion	LSIL	LSIL	CIN-1
Parvathi	35	16544	11	18	17	4	P3L3	5	Leucorrhoea	Normal	Low grade lesion	LSIL	LSIL	CIN-1
Jeeva	42	13919	12	24	18	3	P2L3	18	Leucorrhoea	Ectopy	Normal study	NIL	NIL	Cervicitis
Renuga	38	14219	13	21	17	4	P3L3	13	Low AbdPain	Normal	Metaplasia	NIL	NIL	Cervicitis
Pushpa	37	16778	14	20	17	3	P2L2	13	Men Dis	Normal	Normal study	NIL	NIL	Cervicitis
Sathya	37	16630	12	21	16	5	P3L3	10	Leucorrhoea	Ectopy	Low grade lesion	LSIL	LSIL	CIN-1
Vahithabegum	31	17044	13	13	18	3	Nulli		Leucorroea	Ectopy	Low grade lesion	ASC US	NIL	Cervicitis
Rahamath	40	1118	11	20	20	5	P2L2	15	Screening	Ectopy	Low grade lesion	LSIL	LSIL	CIN-1
Selvi	30	17193	12	13	17	3	P2L2	5	Leucorrhoea	Ectopy	Low grade lesion	LSIL	LSIL	CIN-1
Gunavathi	41	15535	13	22	19	5	P3L3	15	Low AbdPain	Ectopy	Low grade lesion	LSIL	LSIL	CIN-1
Kamala	27	15961	12	8	19	4	P3L3	2	Leucorrhoea	Ectopy	Normal study	NIL	NIL	Cervicitis
Usha	37	14128	14	19	18	3	P3L3	11	Leucorrhoea	Ectopy	Normal study	NIL	NIL	Cervicitis
Jayachitra	38	23248	11	20	18	5	P2L2	17	Leucorrhoea	Ectopy	Low grade lesion	LSIL	LSIL	CIN-1
Saradhammal	38	22873	13	21	17	4	P3L3A1	15	Low AbdPain	Normal	Low grade lesion	LSIL	LSIL	CIN-1
Vijayalakshmi	39	487	12	22	17	3	P2L2A1	14	Leucorrhoea	Ectopy	Normal study	ASC US	NIL	Cervicitis
Rajaveni	42	19012	12	23	19	4	P2L2	15	Leucorrhoea	Normal	Normal study	NIL	NIL	Cervicitis

KEY TO MASTER CHART

CIN	Cervical Intra epithelial Neoplasia
HSIL	High grade Squamous Intra epithelial Lesion
LSIL	Low grade Squamous Intra epithelial Lesion
NIL	Negative for Intra epithelial Lesion
US	Unsatisfactory
LBC	Liquid Based Cytology
ASCUS	Atypical Squamous Cells of Undetermined Signifcance
LCB	Last Child Birth
SES	Socio-Economic Status
Age-men	Age at menarche
Age-mar	Age at marriage
Dur-mar	Duration of marriage
S/E	Speculum Examination

PATIENT CONSENT FORM

Study Details : Comparative analysis of VIA, VILI, Liquiprep TM and conventional Pap Smear with histopathology as Gold Standard

Study Centre : Institute of Social Obstetrics and Govt. Kasturba Gandhi Hospital, Madras Medical College, Chennai.

Patient may check (✓) these boxes

I confirm that I have understood the purpose of procedure for the above study. I have the opportunity to ask question and all my questions and doubts have been answered to my complete satisfaction. ☐

I understand that my participation in the study is voluntary and that I am free to withdraw at any time without giving reason, without my legal rights being affected. ☐

I understand that sponsor of the clinical study, others working on the sponsor's behalf, the ethical committee and the regulatory authorities will not need my permission to look at my health records, both in respect of current study and any further research that may be conducted in relation to it, even if I withdraw from the study I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published, unless as required under the law. I agree not to restrict the use of any data or results that arise from this study. ☐

I agree to take part in the above study and to comply with the instructions given during the study and faithfully cooperate with the study team and to immediately inform the study staff if I suffer from any deterioration in my health or well being or any unexpected or unusual symptoms. ☐

I hereby give permission to undergo complete clinical examination and diagnostic tests including hematological, biochemical, radiological tests. ☐

I hereby consent to participate in this study. ☐

Signature/ Thumb Impression:

Patient Name and Address: Place Date

Signature of Investigator

Study Investigator's Name: Place Date

ஆராய்ச்சி ஒப்புதல் கடிதம்

ஆராய்ச்சி தலைப்பு:

பெயர்	:	தேதி	:
வயது	:	உள்நோயாளி எண்	:
பால்	:	ஆராய்ச்சி சேர்க்கை எண்	:

இந்த ஆராய்ச்சியின் விவரங்களும் அதன் நோக்கம் முழுமையாக எனக்கு தெளிவாக விளக்கப்பட்டது.

எனக்கு விளக்கப்பட்ட விஷயங்களை நான் புரிந்து கொண்டு நான் எனது சம்மதத்தை தருகிறேன்.

எனக்கு பாப் பரிசோதனையும் (Pap Smear), கர்ப்பப்பை வாய் சதை பரிசோதனையும் (Cervix Biopsy) செய்து கொள்ள சம்மதம்

இந்த ஆராய்ச்சியில் பிறரின் நிர்ப்பந்தமின்றி என் சொந்த விருப்பத்தின் பேரில் நான் பங்கு பெறுகிறேன் மற்றும் நான் இந்த ஆராய்ச்சியிலிருந்து எந்நேரமும் பின்வாங்கலாம் என்பதையும் அதனால் எந்த பாதிப்பும் ஏற்படாது என்பதையும் நான் புரிந்து கொண்டேன்.

நான் பாப் பரிசோதனை (Pap Smear), கர்ப்பப்பை வாய் சதை பரிசோதனை (Cervix Biopsy) பற்றிய விவரங்களைக் கொண்ட தகவல் தாளைப் பெற்றுக்கொண்டேன்.

நான் என்னுடைய சுயநினைவுடன் மற்றும் முழு சுதந்திரத்துடன் இந்த மருத்துவ ஆராய்ச்சியில் என்னை சேர்த்துக் கொள்ள சம்மதிக்கிறேன்.

எனக்கு அறுவை சிகிச்சை செய்யப்பட்டு நோய்க்குறியியல் துறையில் சதைப் பரிசோதனைக்கு பயன்பட்ட மெழுகுக்கட்டிகளை வைத்து ஆராய்ச்சி மற்றும் சிறப்பு பரிசோதனை செய்து கொள்ள சம்மதம் தெரிவிக்கிறேன்.

சதைப் பரிசோதனை செய்வதற்கு முன் வலி தெரியாமல் இருப்பதற்காக ஊசி (லிக்னொகெய்ன் இஞ்செக்ஷன்) போடுவதற்கும் சம்மதிக்கிறேன். மேற்கொண்ட ஊசி போடுவதற்கு முன் ஒவ்வாமை (அலெர்ஜி) பரிசோதிக்க, மேற்கண்ட ஊசியை தோலில் போட்டுக் கொள்ளவும் சம்மதிக்கிறேன்.

மேற்கண்ட ஊசியை போடும் போதோ அல்லது சதை பரிசோதனை செய்யும் போதோ ஏதேனும் பின் விளைவுகள் (அரிப்பு, தோல் வீக்கம், மயக்கம், தலைச்சுற்றல், வாந்தி முதலியன) ஏற்படலாம் என மருத்துவர் மூலம் தெரிந்து கொண்டேன்.

கையொப்பம்